US006289239B1

(12) **United States Patent**
Panescu et al.

(10) **Patent No.: US 6,289,239 B1**
(45) **Date of Patent: Sep. 11, 2001**

(54) **INTERACTIVE SYSTEMS AND METHODS FOR CONTROLLING THE USE OF DIAGNOSTIC OR THERAPEUTIC INSTRUMENTS IN INTERIOR BODY REGIONS**

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(73) Assignee: **Boston Scientific Corporation**, San Jose, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **09/538,133**

(22) Filed: **Mar. 29, 2000**

Related U.S. Application Data

(63) Continuation of application No. 09/048,629, filed on Mar. 26, 1998, now Pat. No. 6,106,460.

(51) **Int. Cl.**[7] **A61B 5/044**
(52) **U.S. Cl.** **600/523**
(58) **Field of Search** 128/920; 600/300, 600/523, 525

(56) **References Cited**

U.S. PATENT DOCUMENTS

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5,687,737	11/1997	Branham et al.	128/710
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6,106,460 *	8/2000	Panescu et al.	600/300

FOREIGN PATENT DOCUMENTS

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WO 95/15521	6/1995	(WO) .
WO 96/34571	11/1996	(WO) .

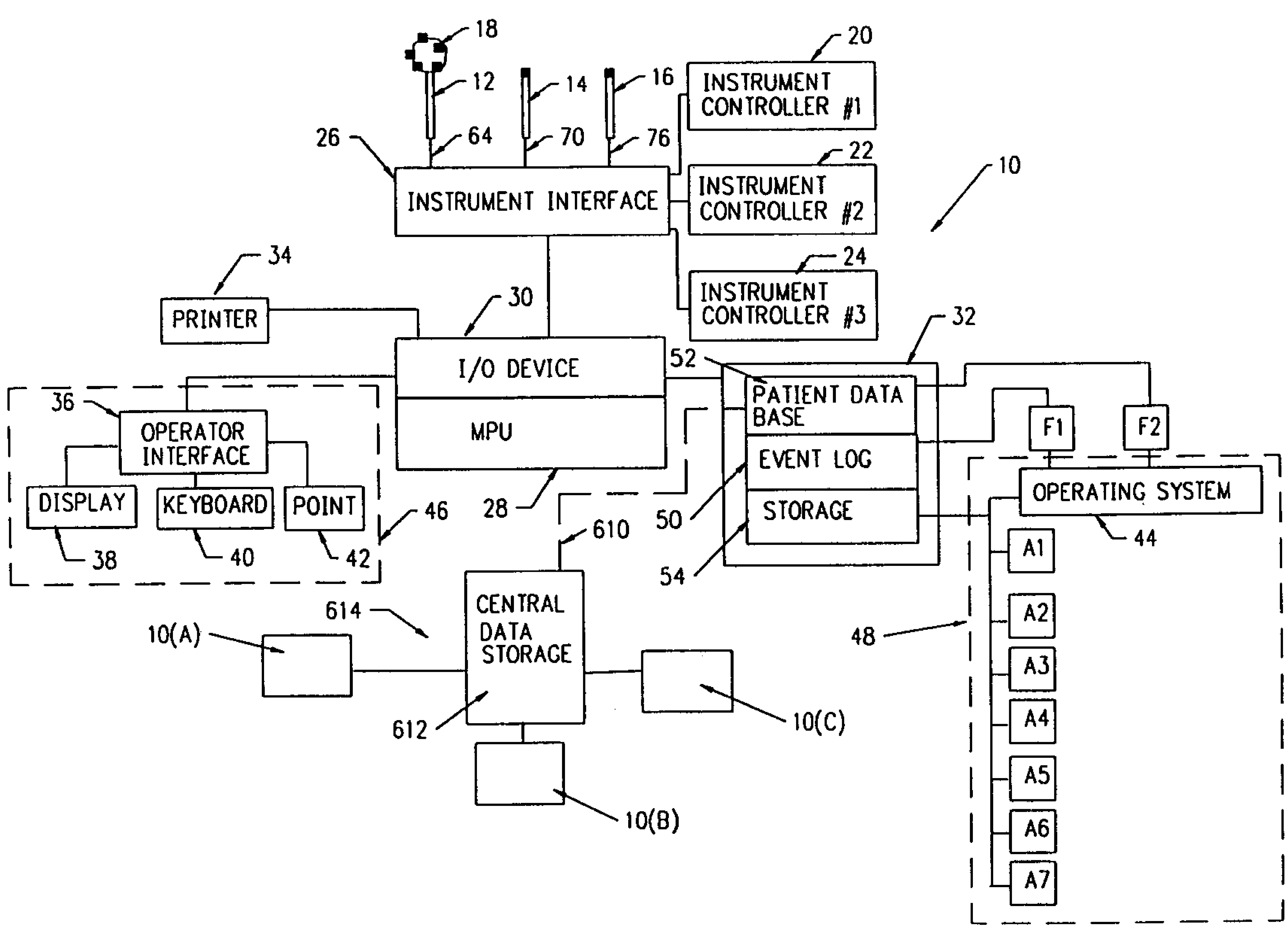
* cited by examiner

Primary Examiner—William E. Kamm
(74) *Attorney, Agent, or Firm*—Lyon & Lyon LLP

(57) **ABSTRACT**

An interface is associated with a structure which, in use, is deployed in an interior body region of a patient. The structure includes an operative element coupled to a controller, which establishes an operating condition for the operative element to perform a diagnostic or therapeutic procedure in the interior body region. The interface generates a first display comprising an image of the structure at least partially while the operative element performs the procedure. The interface also generates a second display comprising one or more data fields reflecting the operating condition of the controller. The interface enables selection of the first display or the second display for viewing on a display screen.

42 Claims, 32 Drawing Sheets



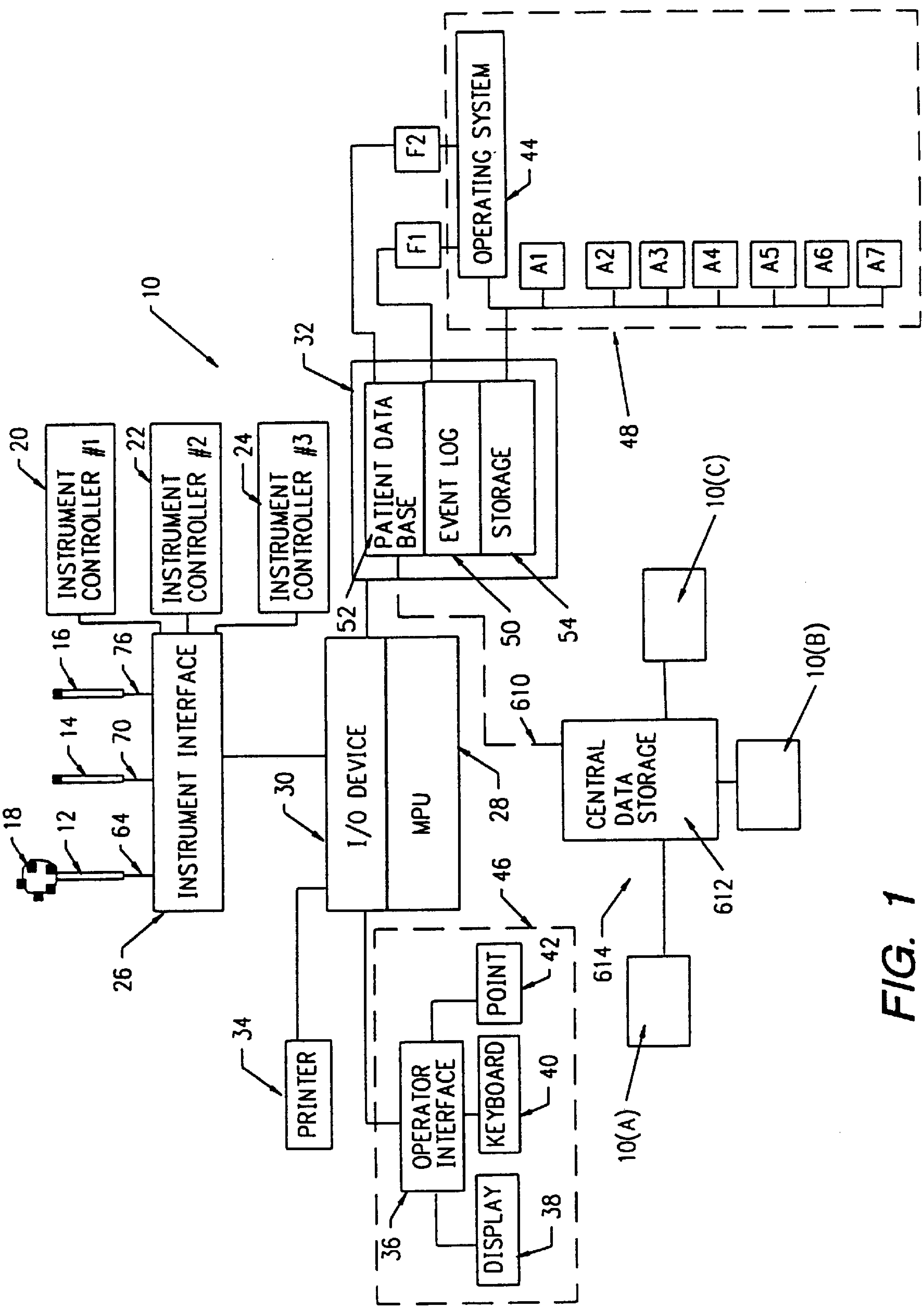

INSTRUMENT CONTROLLER #1
INSTRUMENT CONTROLLER #2
INSTRUMENT CONTROLLER #3
INSTRUMENT INTERFACE
I/O DEVICE
MPU
PRINTER
OPERATOR INTERFACE
POINT
KEYBOARD
DISPLAY
PATIENT DATA BASE
EVENT LOG
STORAGE
OPERATING SYSTEM
F1
F2
A1
A2
A3
A4
A5
A6
A7
CENTRAL DATA STORAGE
10(A)
10(B)
10(C)
10
12
14
16
18
20
22
24
26
28
30
32
34
36
38
40
42
44
46
48
50
52
54
64
70
76
610
612
614

FIG. 1

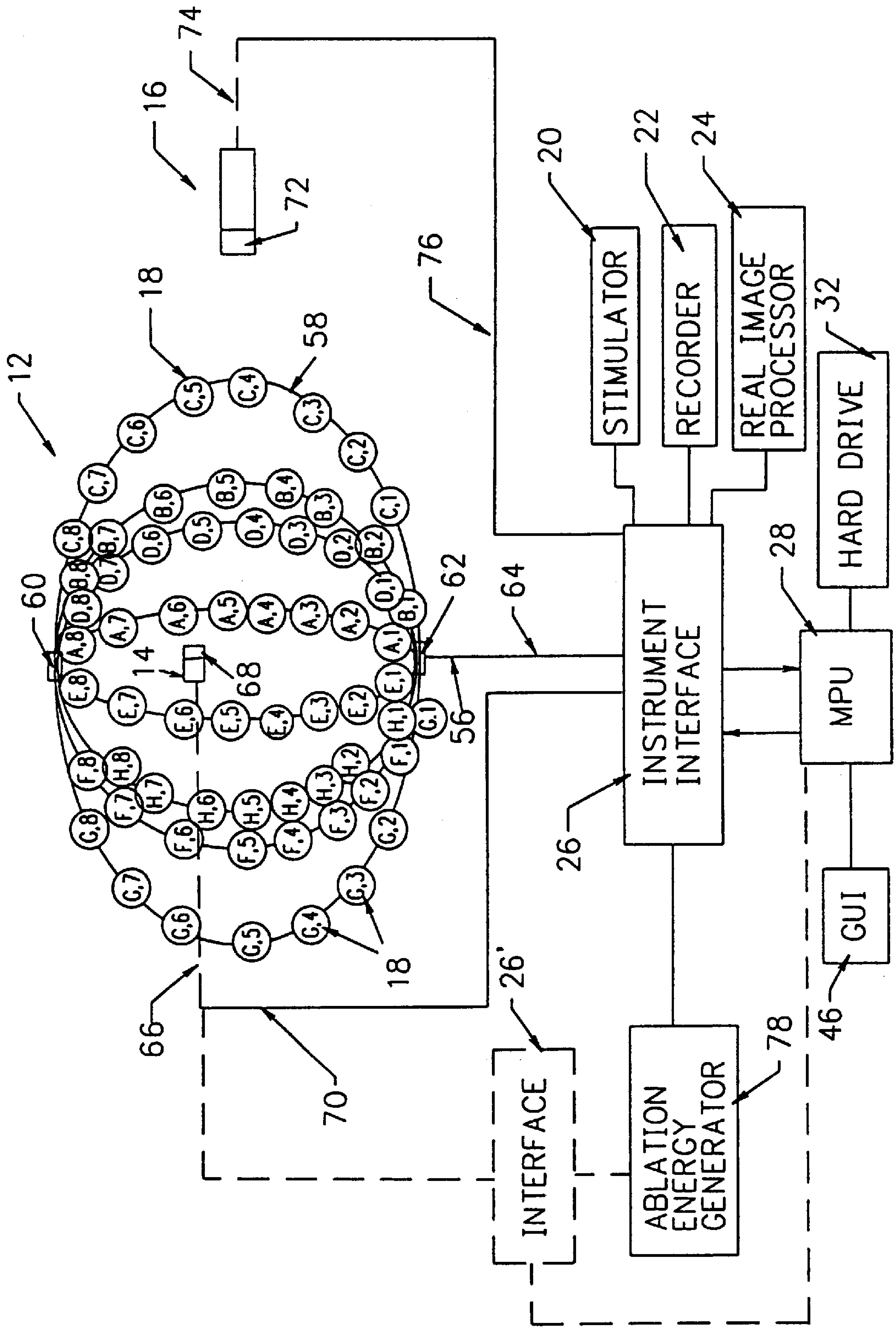
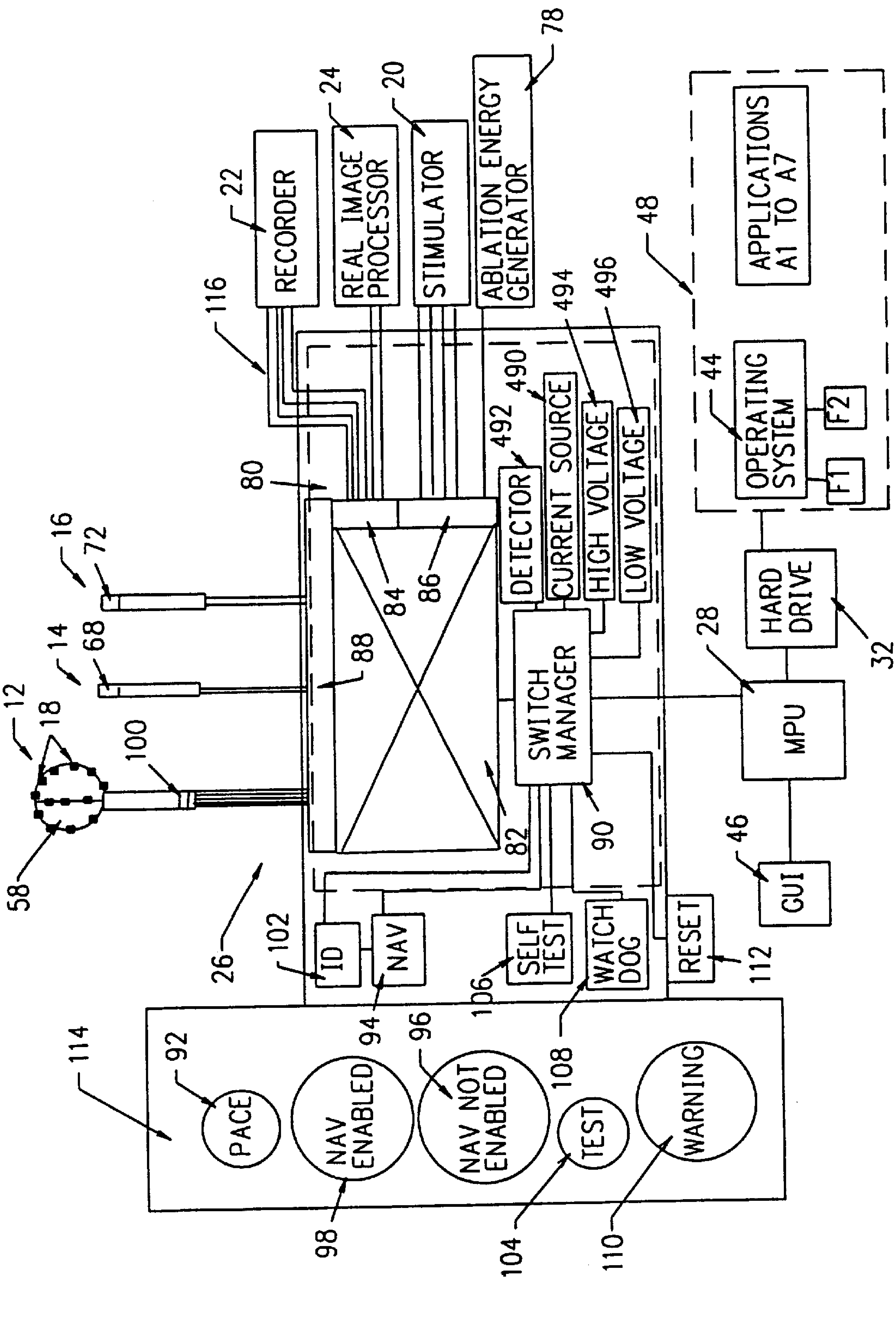

STIMULATOR
RECORDER
REAL IMAGE PROCESSOR
HARD DRIVE
INSTRUMENT INTERFACE
MPU
GUI
ABLATION ENERGY GENERATOR
INTERFACE

FIG. 2



RECORDER
REAL IMAGE PROCESSOR
STIMULATOR
ABLATION ENERGY GENERATOR
APPLICATIONS A1 TO A7
OPERATING SYSTEM
F1
F2
DETECTOR
CURRENT SOURCE
HIGH VOLTAGE
LOW VOLTAGE
SWITCH MANAGER
HARD DRIVE
MPU
GUI
ID
NAV
SELF TEST
WATCH DOG
RESET
PACE
NAV ENABLED
NAV NOT ENABLED
TEST
WARNING
12
18
58
100
14
68
16
72
88
84
86
82
80
116
22
24
20
78
48
44
490
492
494
496
90
28
32
46
26
102
106
108
112
114
92
94
96
98
104
110

FIG. 3

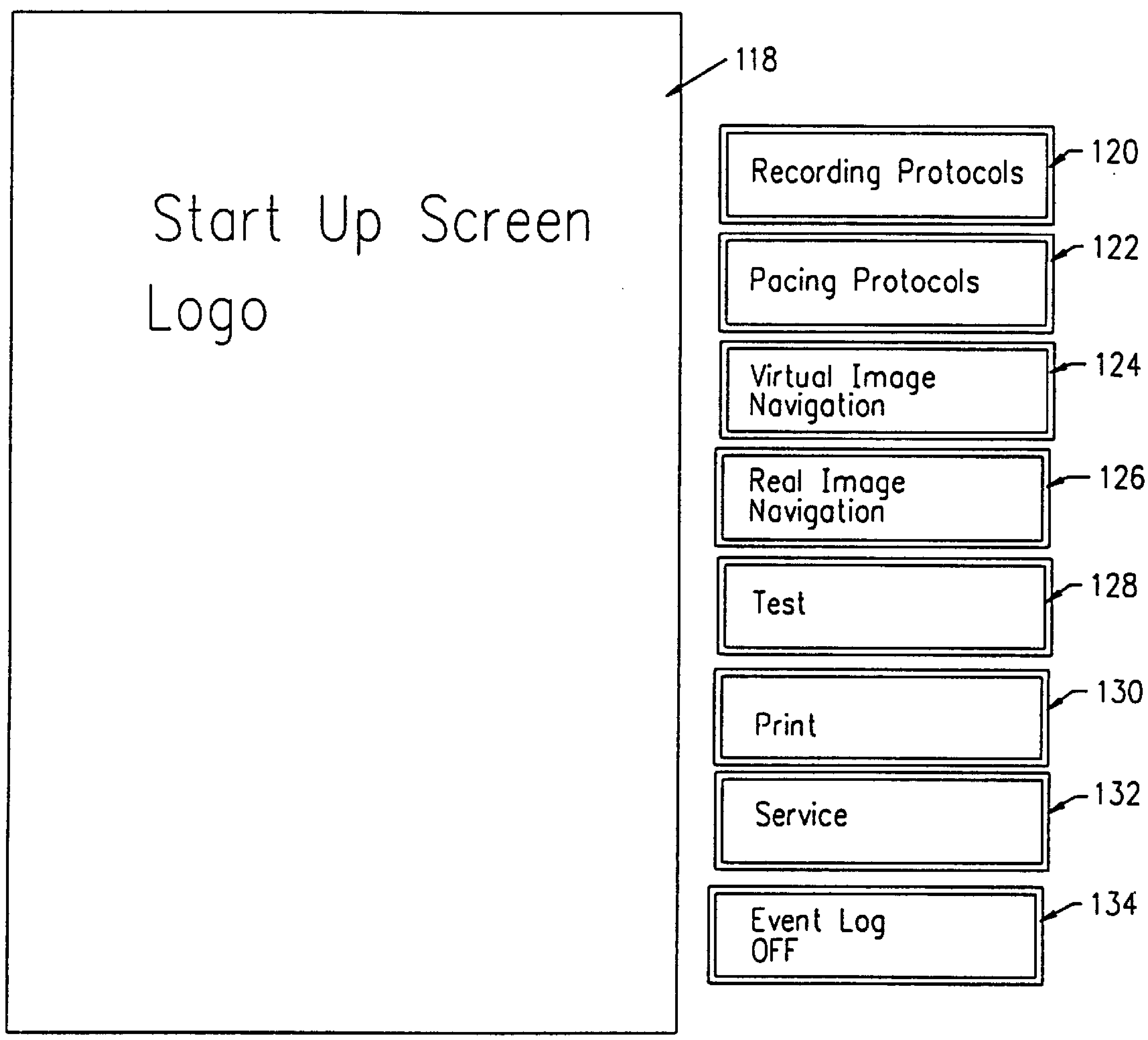

Start Up Screen
Logo
118
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 4

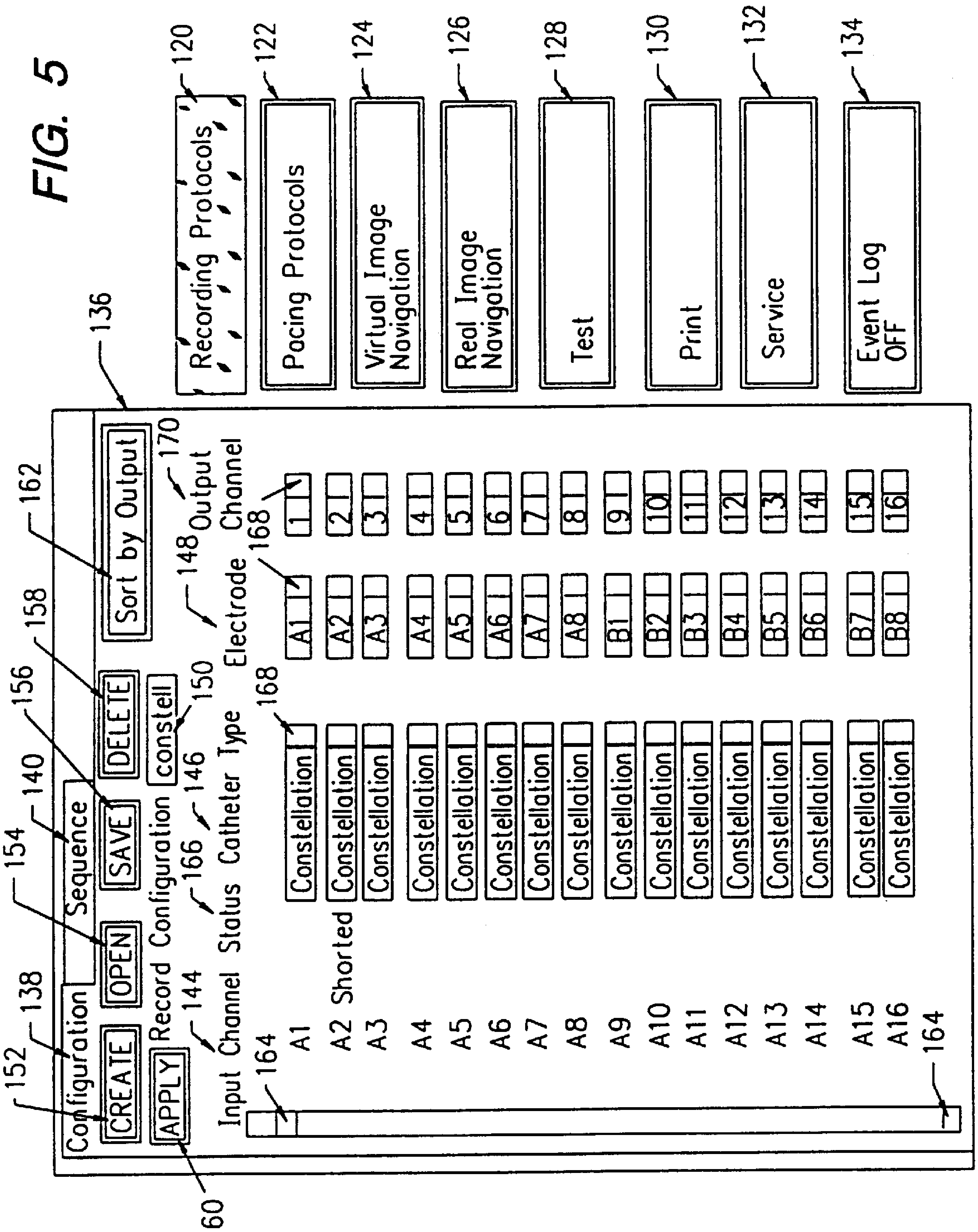

Recording Protocols
Pacing Protocols
Virtual Image Navigation
Real Image Navigation
Test
Print
Service
Event Log OFF
Configuration
Sequence
CREATE
OPEN
SAVE
DELETE
Sort by Output
APPLY
Record Configuration
constell
Input Channel
Status
Catheter Type
Electrode
Output Channel
A1
A2 Shorted
A3
A4
A5
A6
A7
A8
A9
A10
A11
A12
A13
A14
A15
A16
Constellation
A1 A2 A3 A4 A5 A6 A7 A8 B1 B2 B3 B4 B5 B6 B7 B8
1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16
120
122
124
126
128
130
132
134
136
138
140
144
146
148
150
152
154
156
158
160
162
164
166
168
170

FIG. 5

FIG. 6

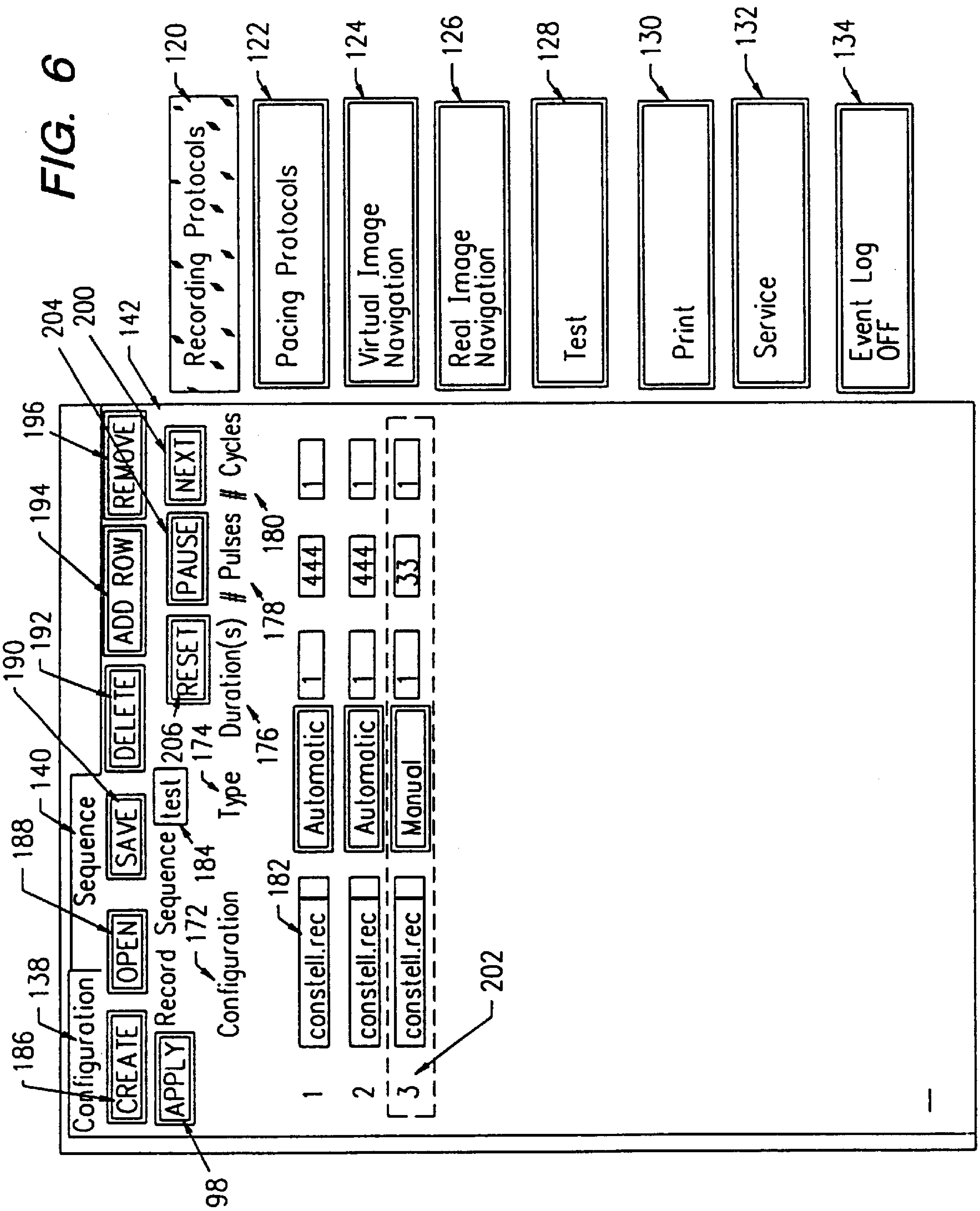
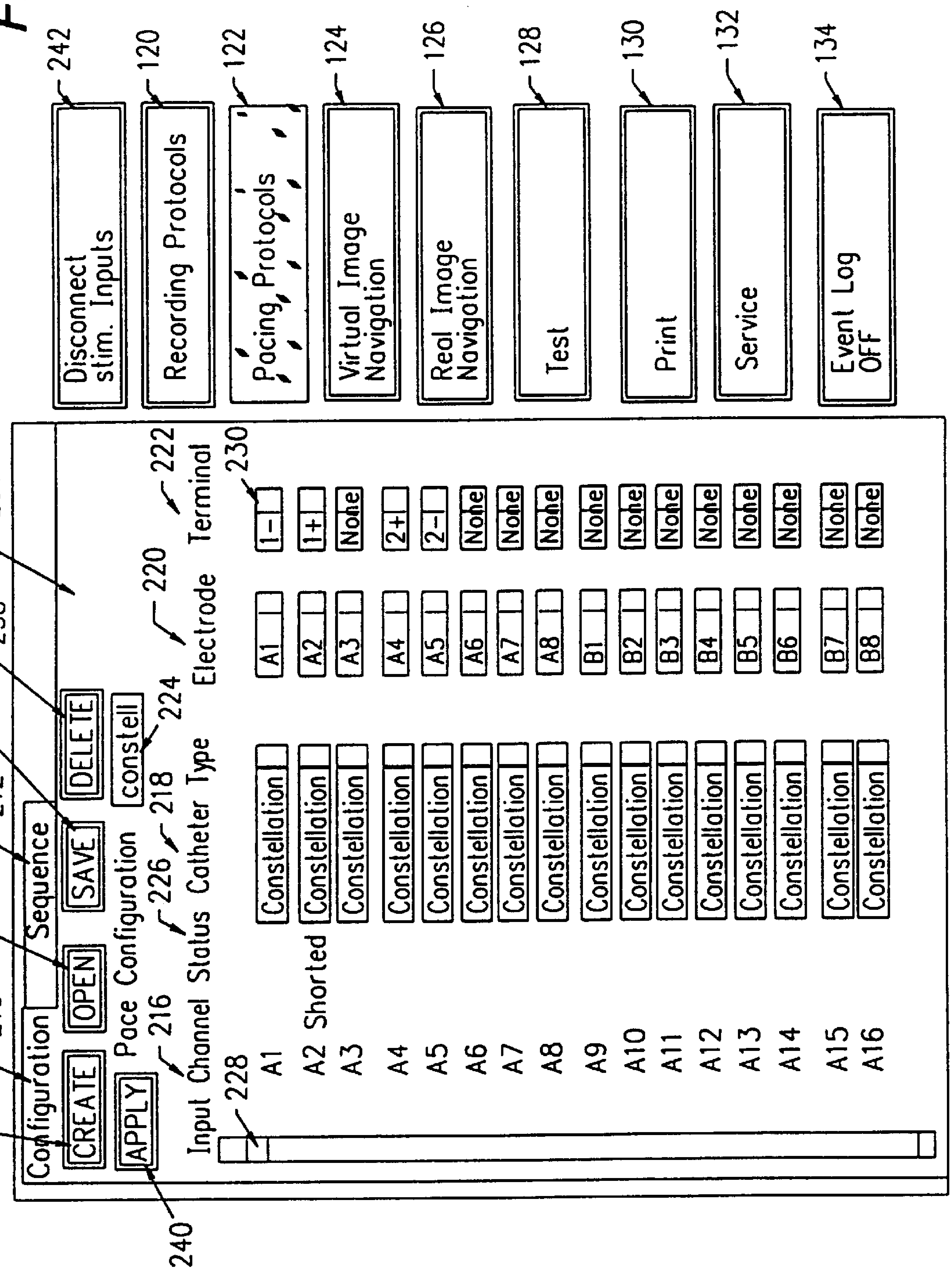
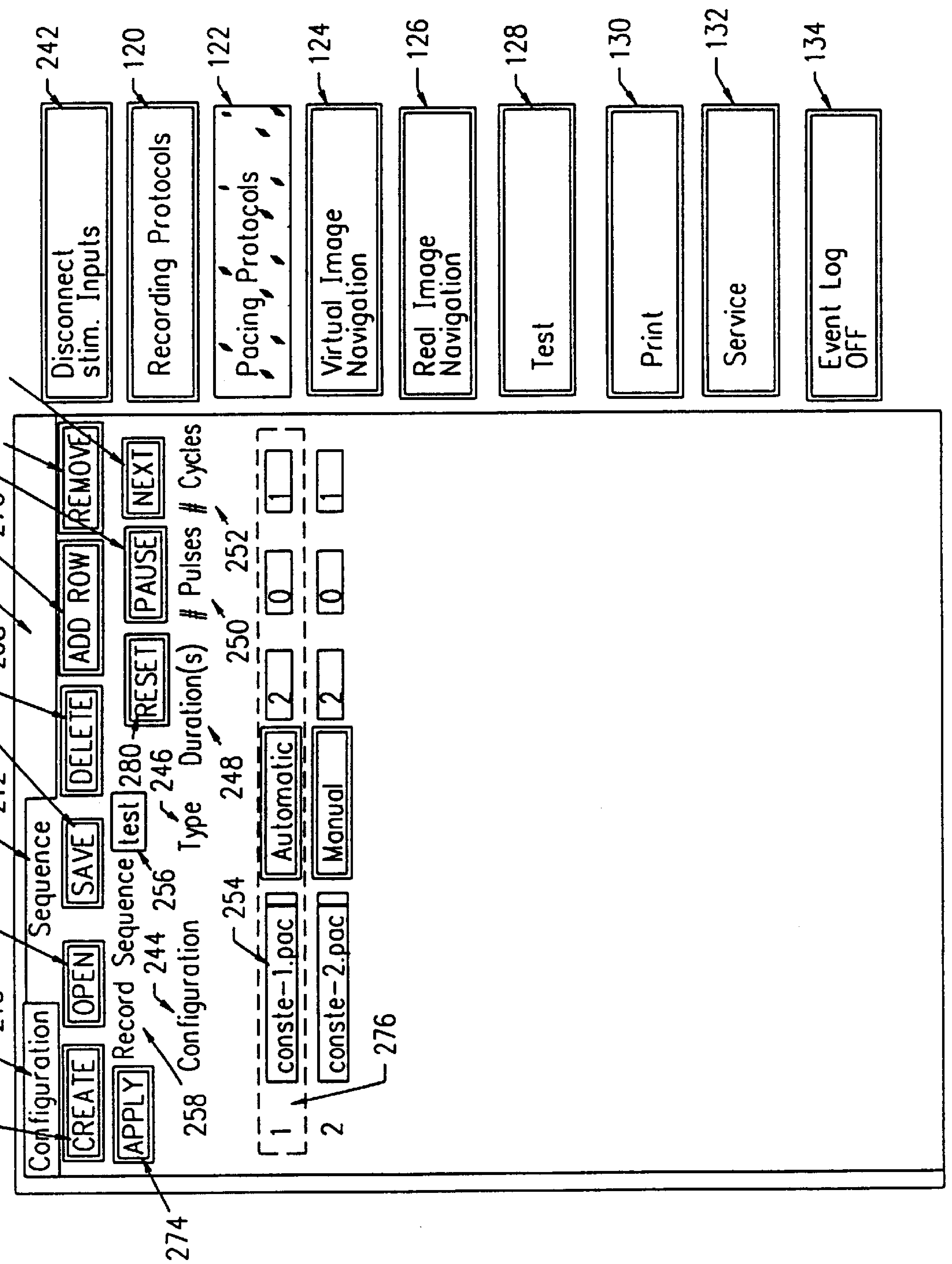

Configuration
Sequence
CREATE
OPEN
SAVE
DELETE
ADD ROW
REMOVE
APPLY
Record Sequence
test
RESET
PAUSE
NEXT
Configuration
Type
Duration(s)
# Pulses
# Cycles
1
2
3
constell.rec
Automatic
Automatic
Manual
444
444
33
Recording Protocols
Pacing Protocols
Virtual Image Navigation
Real Image Navigation
Test
Print
Service
Event Log OFF
120
122
124
126
128
130
132
134
138
140
142
172
174
176
178
180
182
184
186
188
190
192
194
196
198
200
202
204
206

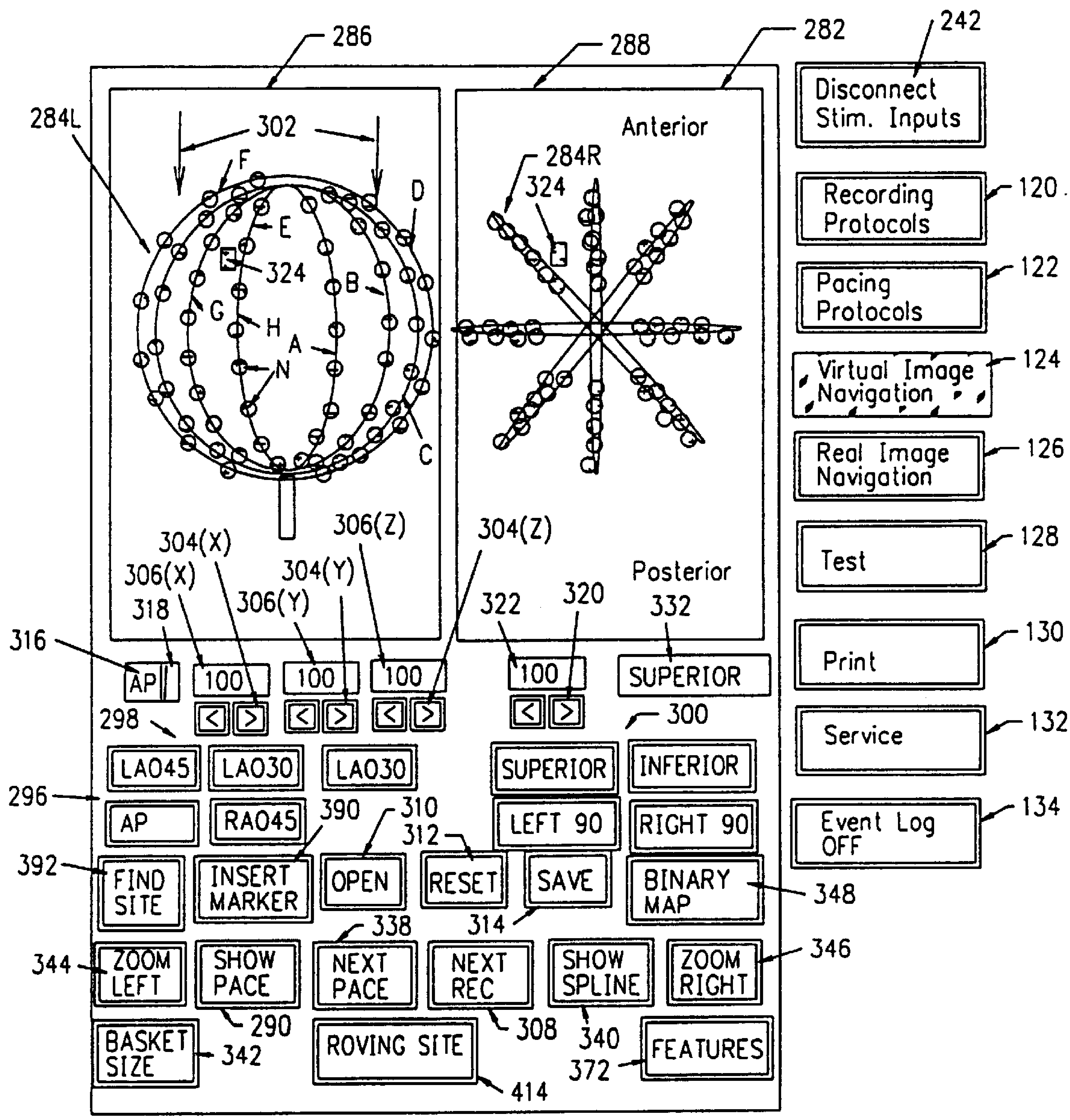
FIG. 7



Disconnect stim. Inputs
Recording Protocols
Pacing Protocols
Virtual Image Navigation
Real Image Navigation
Test
Print
Service
Event Log OFF
Configuration
Sequence
CREATE
OPEN
SAVE
DELETE
APPLY
Pace Configuration
constell
Input Channel Status Catheter Type Electrode Terminal
A1
A2 Shorted
A3
A4
A5
A6
A7
A8
A9
A10
A11
A12
A13
A14
A15
A16
Constellation
A1
A2
A3
A4
A5
A6
A7
A8
B1
B2
B3
B4
B5
B6
B7
B8
1−
1+
None
2+
2−
242
120
122
124
126
128
130
132
134
208
210
212
216
218
220
222
224
226
228
230
232
234
236
238
240

FIG. 8


Disconnect stim. Inputs
Recording Protocols
Pacing Protocols
Virtual Image Navigation
Real Image Navigation
Test
Print
Service
Event Log OFF
Configuration
Sequence
CREATE
OPEN
SAVE
DELETE
ADD ROW
REMOVE
APPLY
Record Sequence
test
RESET
PAUSE
NEXT
Configuration
Type
Duration(s)
# Pulses
# Cycles
1
conste-1.pac
Automatic
2
0
1
2
conste-2.pac
Manual
2
0
1
242
120
122
124
126
128
130
132
134
210
212
214
244
246
248
250
252
254
256
258
260
262
264
266
268
270
272
274
276
278
280



286
288
282
242
Disconnect Stim. Inputs
284L
302
F
D
E
324
B
G
H
A
N
C
Anterior
284R
324
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
304(X)
306(X)
318
316
306(Z)
304(Y)
306(Y)
304(Z)
322
320
Posterior
332
AP
100
100
100
100
SUPERIOR
298
300
LAO45
LAO30
LAO30
SUPERIOR
INFERIOR
296
AP
RA045
390
310
312
LEFT 90
RIGHT 90
392
FIND SITE
INSERT MARKER
OPEN
RESET
SAVE
BINARY MAP
348
338
314
344
ZOOM LEFT
SHOW PACE
NEXT PACE
NEXT REC
SHOW SPLINE
ZOOM RIGHT
346
290
308
340
BASKET SIZE
342
ROVING SITE
372
FEATURES
414

FIG. 9

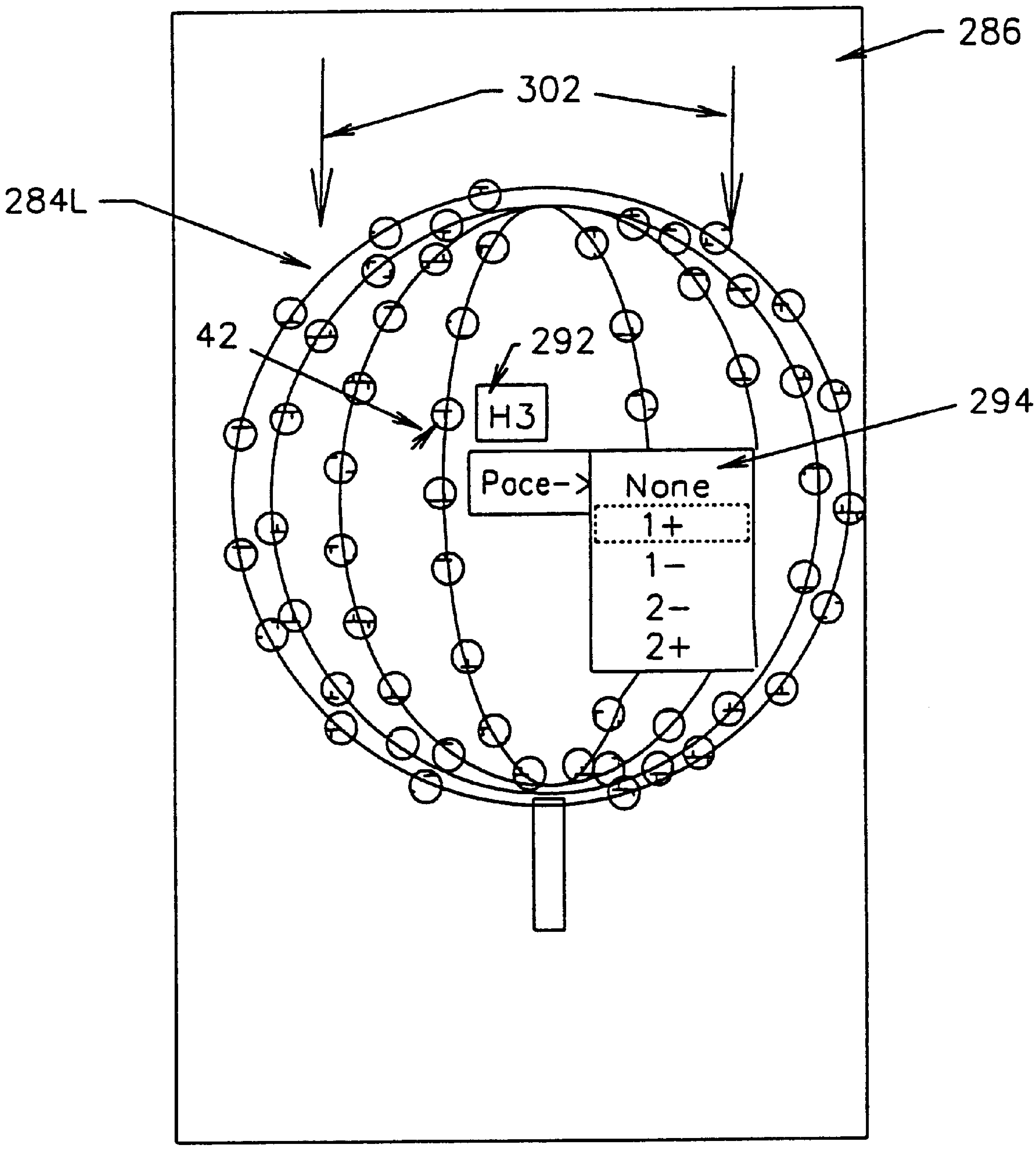


FIG. 10

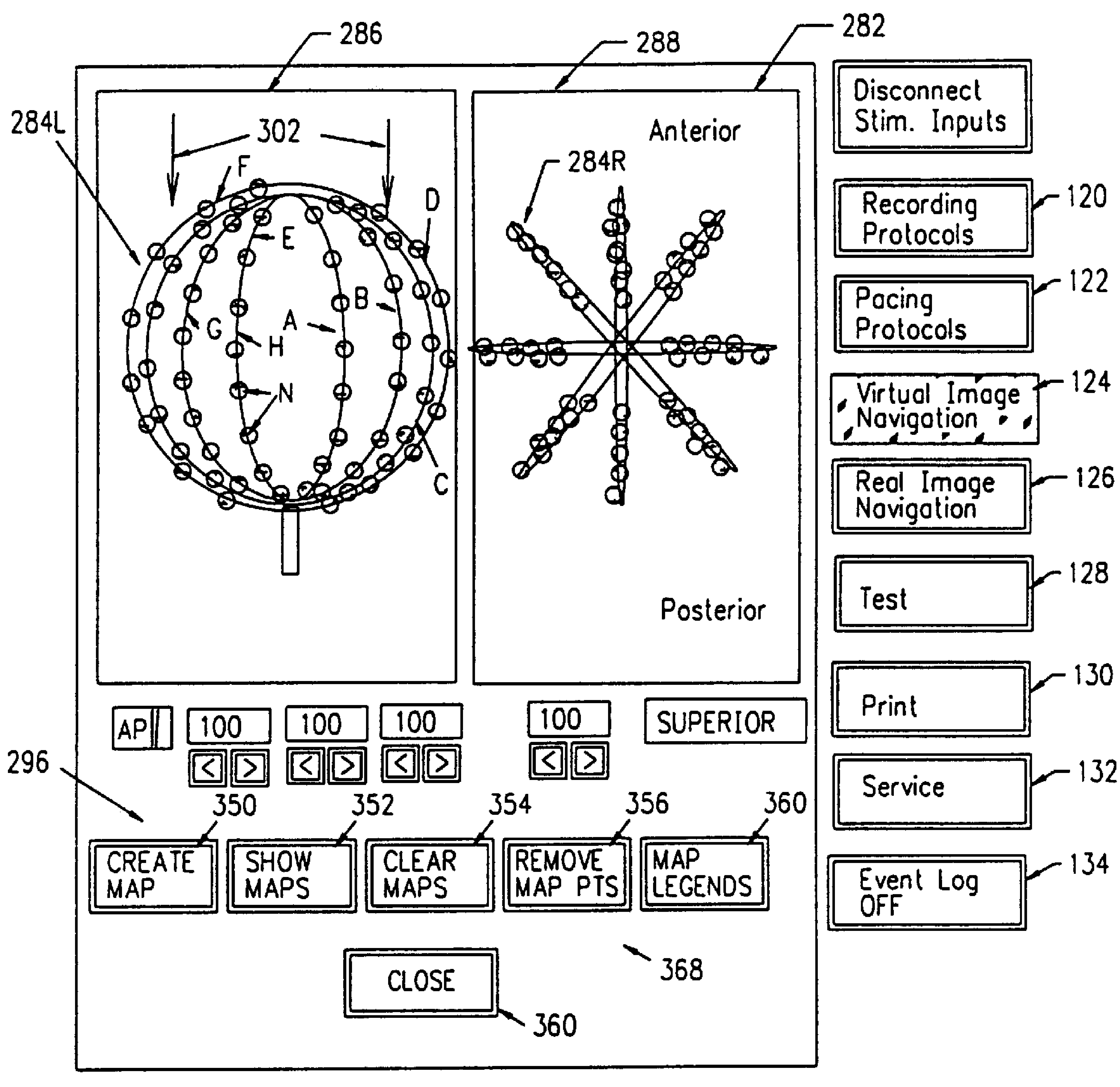

286
288
282
284L
302
F
D
E
B
A
G
H
N
C
Anterior
284R
Posterior
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
AP
100
100
100
100
SUPERIOR
296
350
352
354
356
360
CREATE MAP
SHOW MAPS
CLEAR MAPS
REMOVE MAP PTS
MAP LEGENDS
CLOSE
368
360

FIG. 11

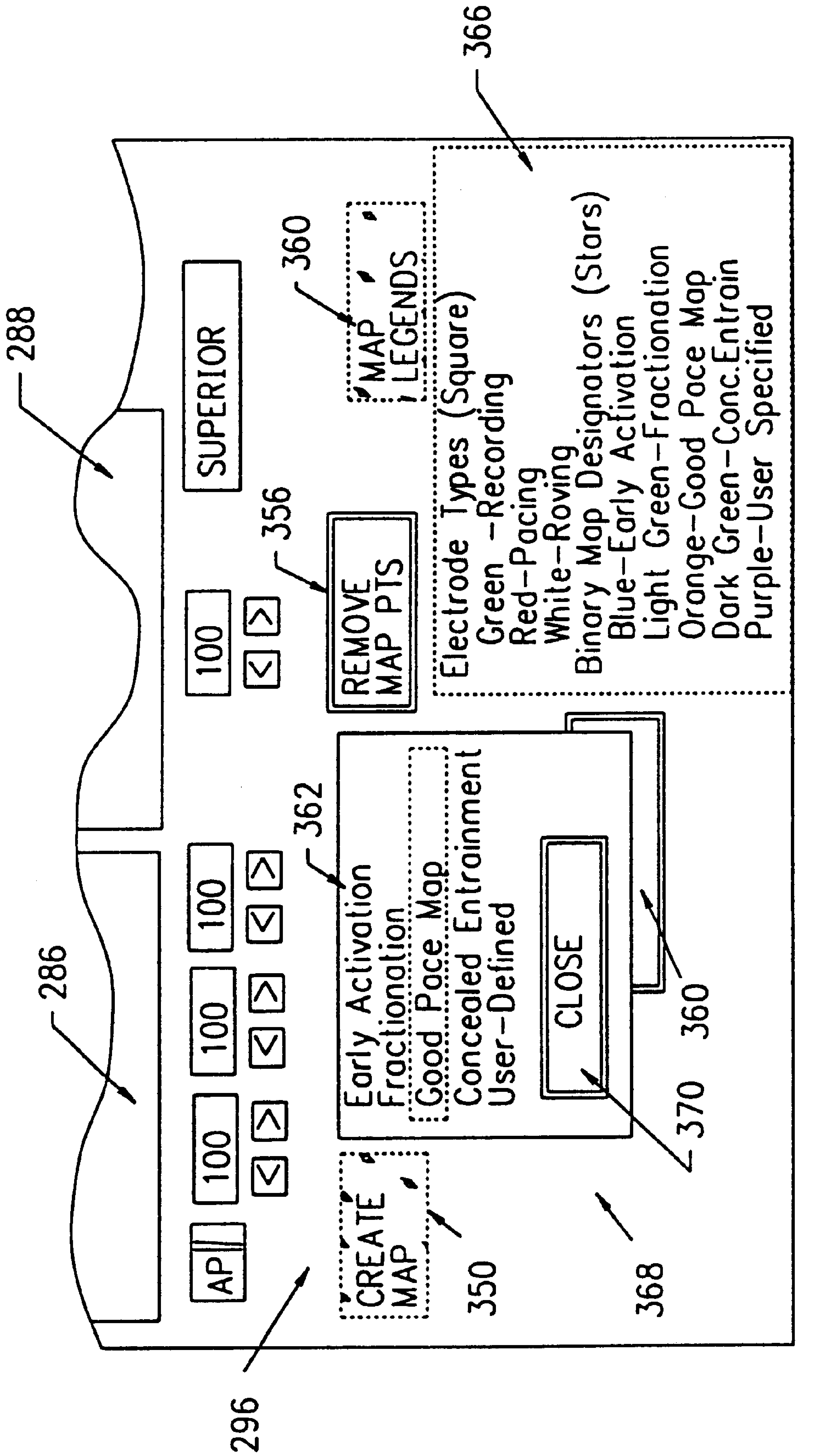
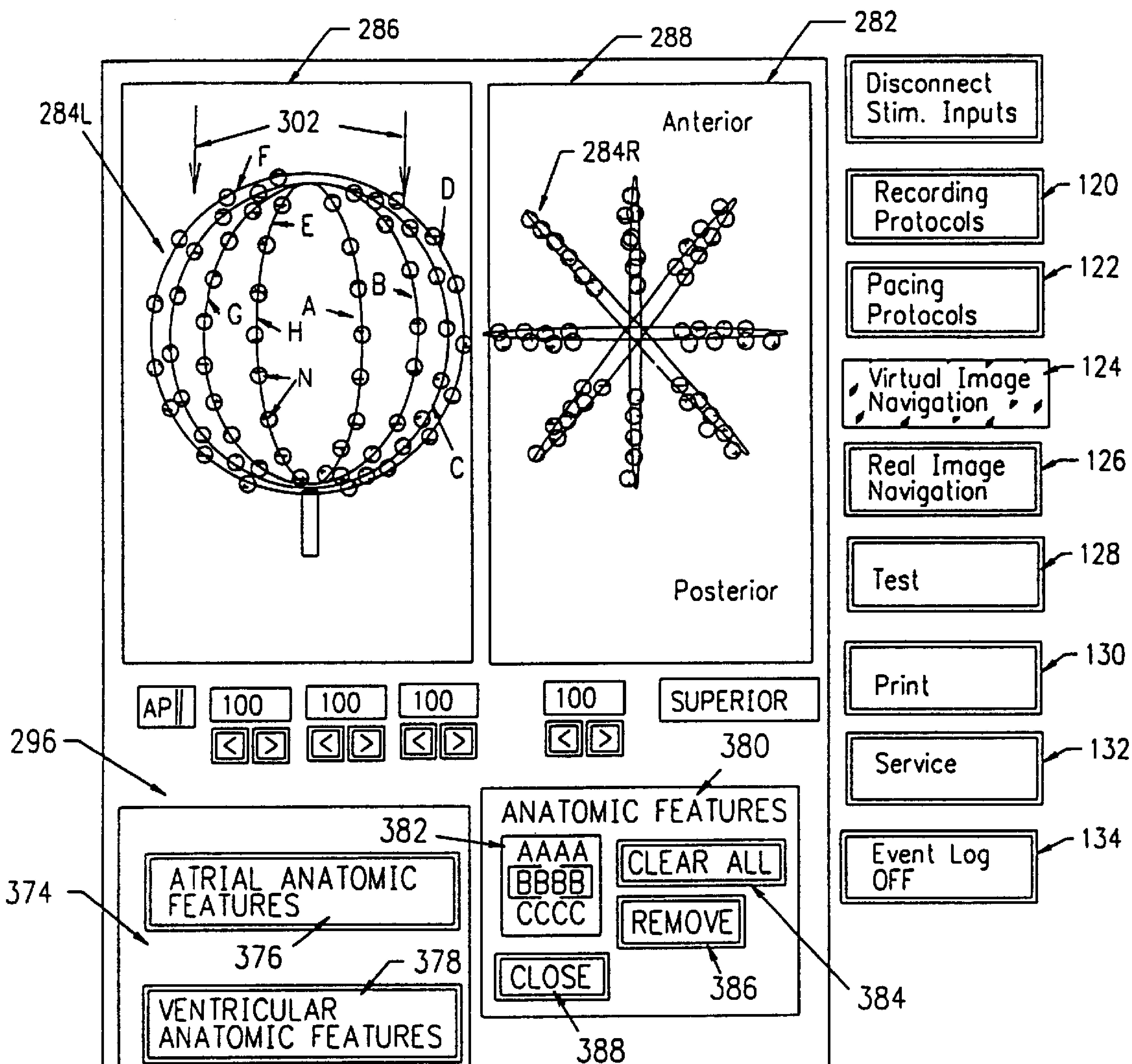

288
286
296
SUPERIOR
AP
100
100
100
100
CREATE MAP
350
REMOVE MAP PTS
356
MAP LEGENDS
360
362
Early Activation
Fractionation
Good Pace Map
Concealed Entrainment
User-Defined
CLOSE
370
360
368
366
Electrode Types (Square)
Green -Recording
Red-Pacing
White-Roving
Binary Map Designators (Stars)
Blue-Early Activation
Light Green-Fractionation
Orange-Good Pace Map
Dark Green-Conc.Entrain
Purple-User Specified

FIG. 12



286
288
282
284L
302
F
D
E
B
A
G
H
N
C
Anterior
284R
Posterior
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
AP
100
100
100
100
SUPERIOR
380
296
382
ANATOMIC FEATURES
AAAA
BBBB
CCCC
CLEAR ALL
REMOVE
CLOSE
386
384
388
374
ATRIAL ANATOMIC FEATURES
376
378
VENTRICULAR ANATOMIC FEATURES

FIG. 13

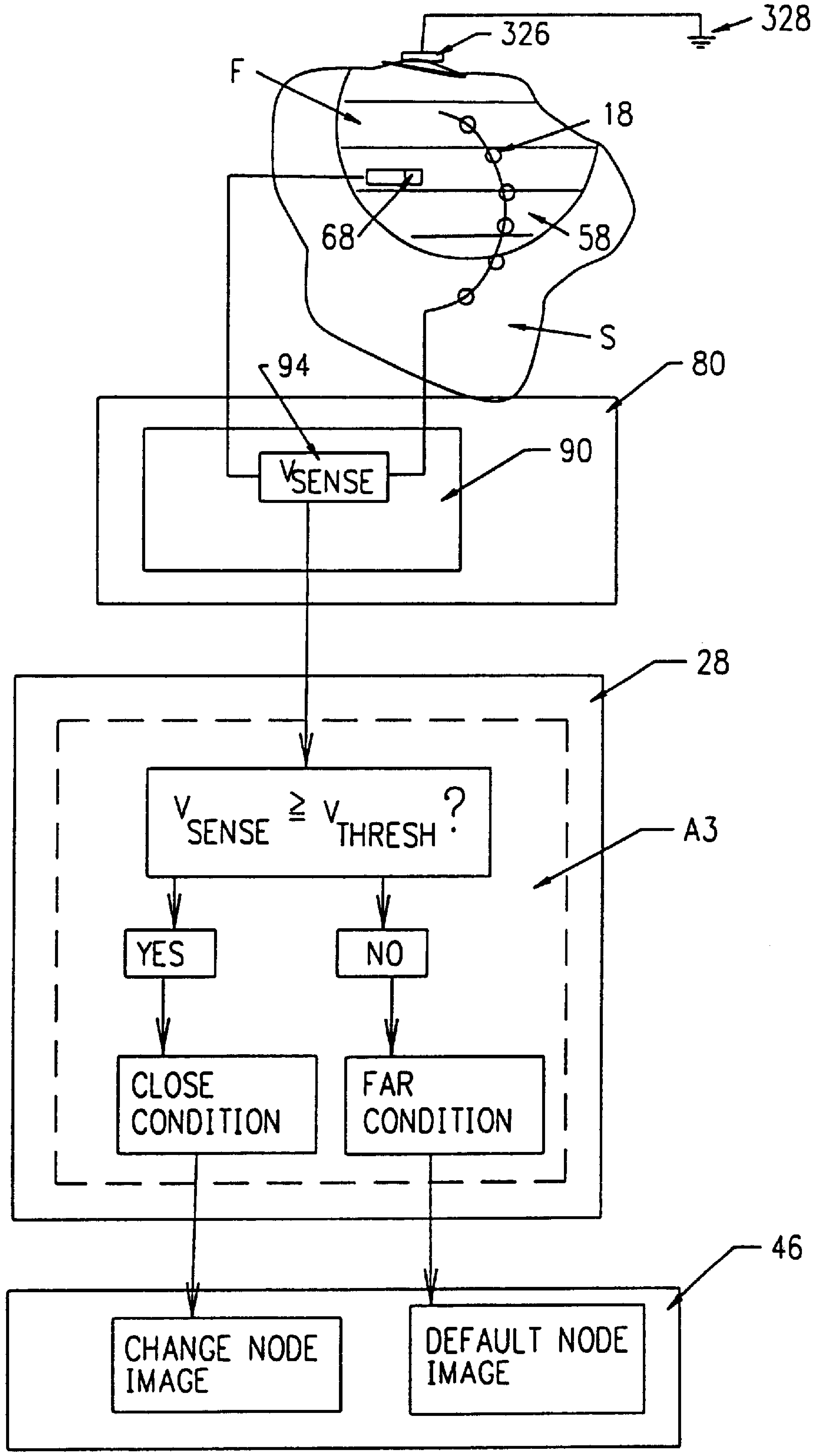

326
328
F
18
68
58
S
94
80
V_{SENSE}
90
28
$V_{SENSE} \geq V_{THRESH}$?
A3
YES
NO
CLOSE CONDITION
FAR CONDITION
46
CHANGE NODE IMAGE
DEFAULT NODE IMAGE

FIG. 14

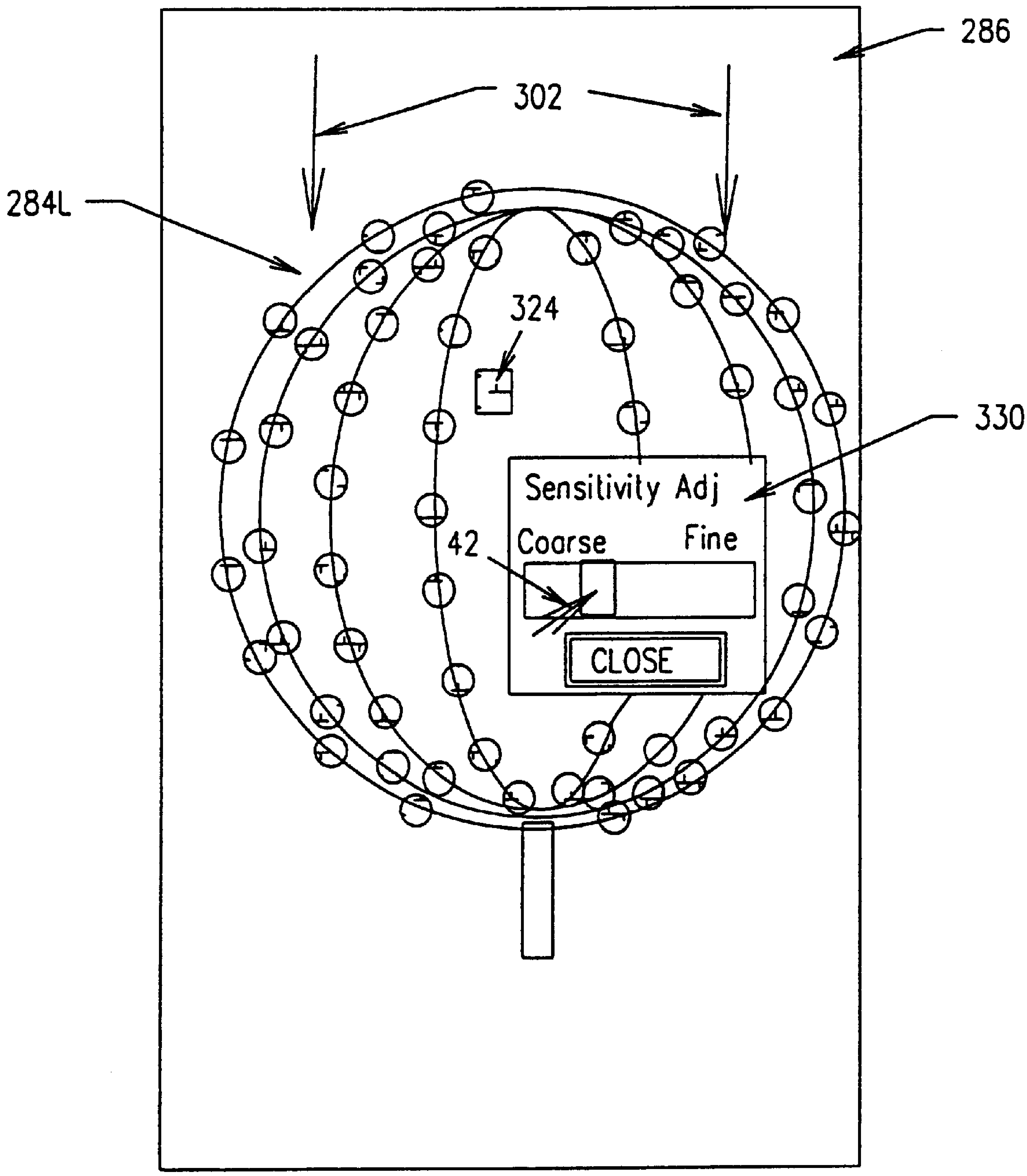


FIG. 15

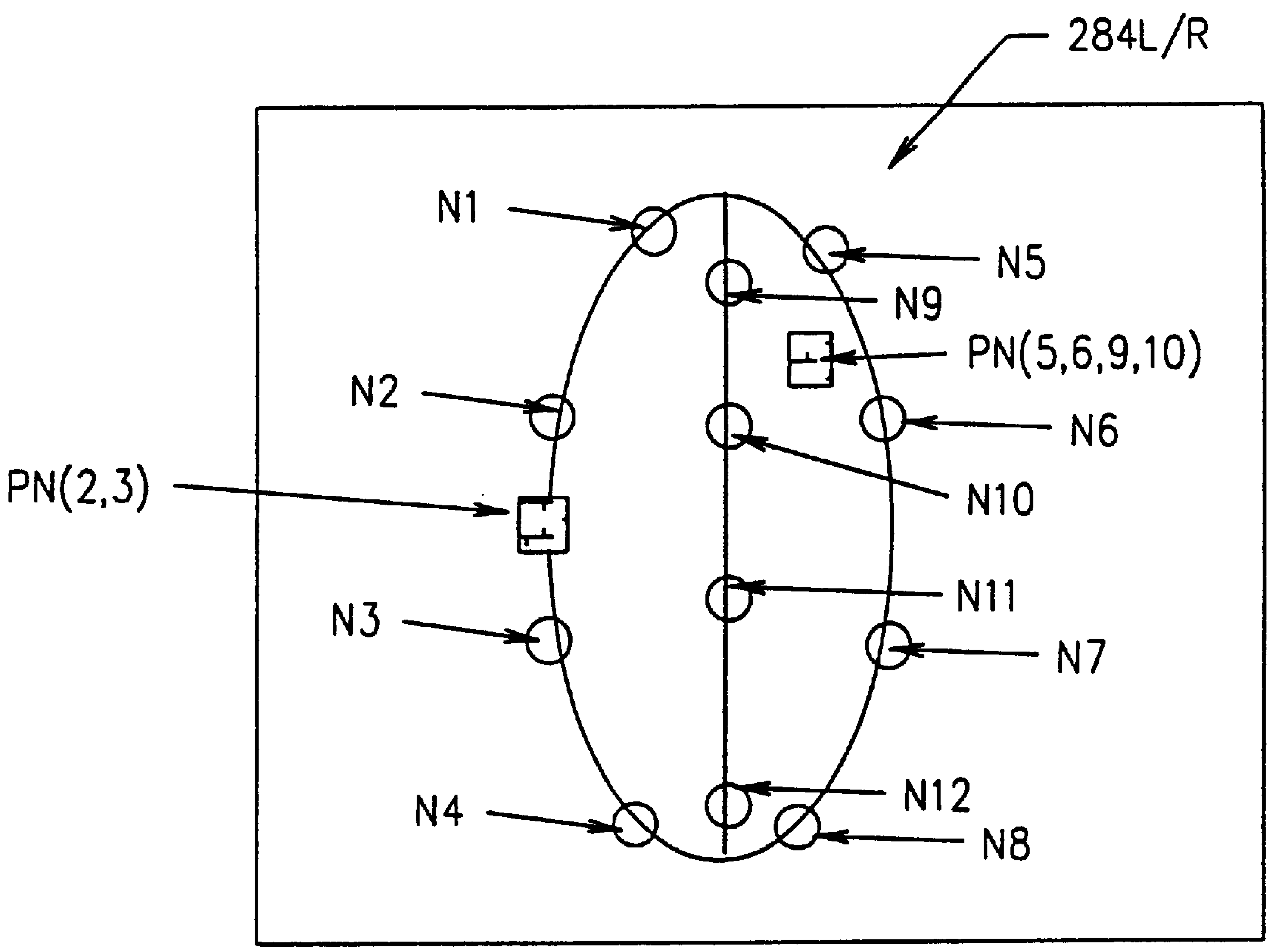


FIG. 16

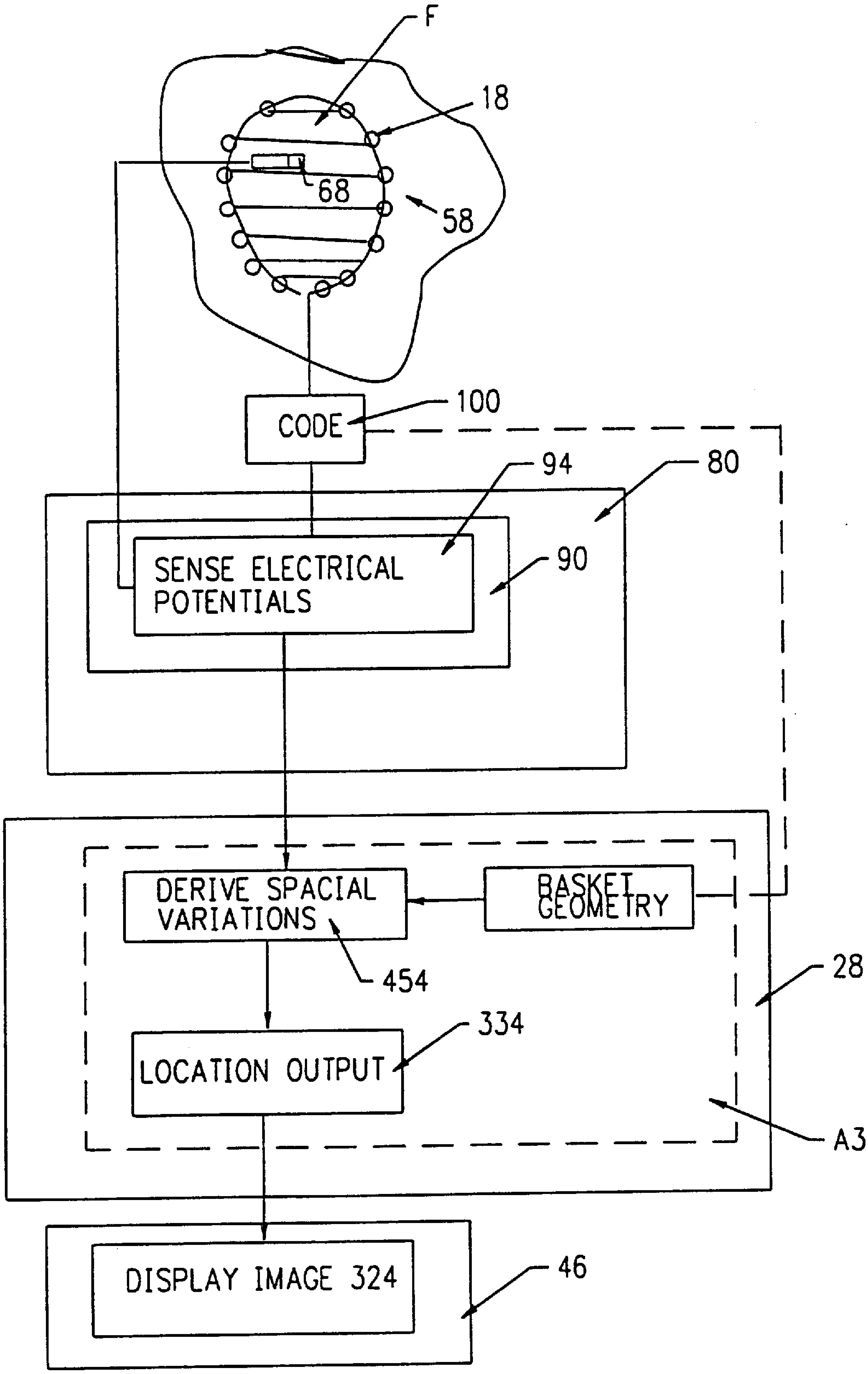

F
18
68
58
CODE
100
94
80
SENSE ELECTRICAL POTENTIALS
90
DERIVE SPACIAL VARIATIONS
BASKET GEOMETRY
454
28
334
LOCATION OUTPUT
A3
DISPLAY IMAGE 324
46

FIG. 17

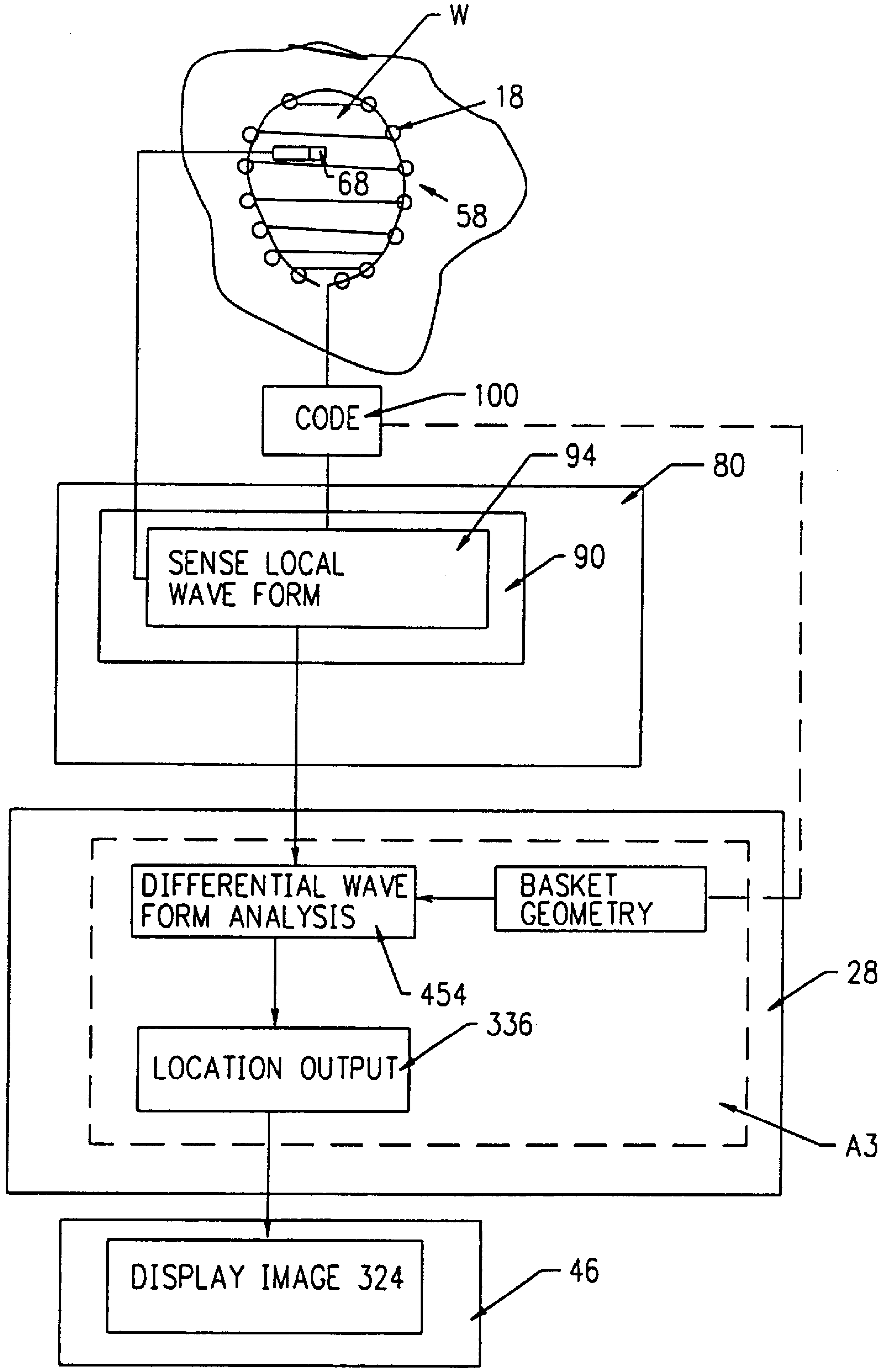

W
18
68
58
100
CODE
94
80
90
SENSE LOCAL
WAVE FORM
DIFFERENTIAL WAVE
FORM ANALYSIS
BASKET
GEOMETRY
28
454
336
LOCATION OUTPUT
A3
DISPLAY IMAGE 324
46

FIG. 18

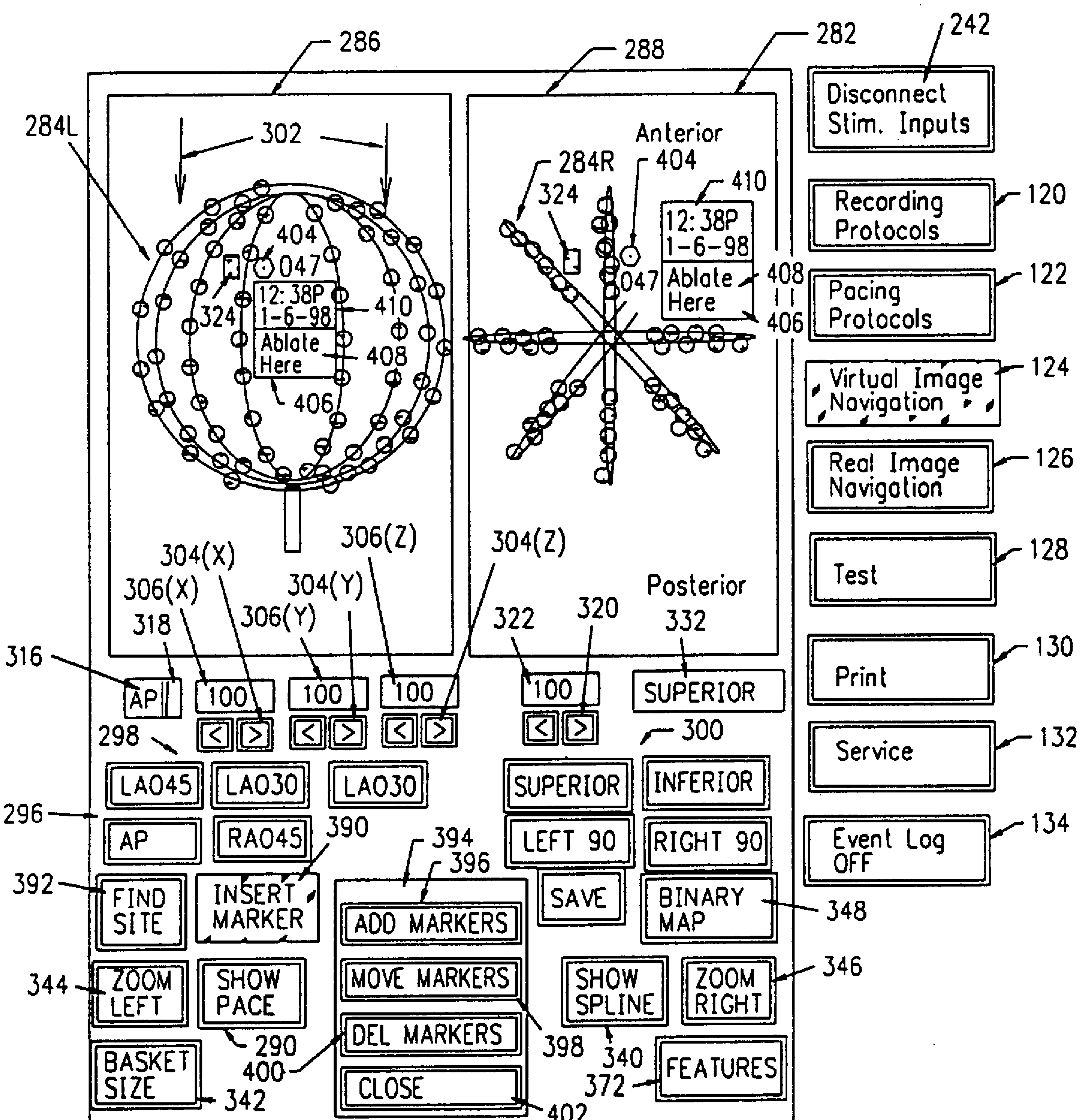
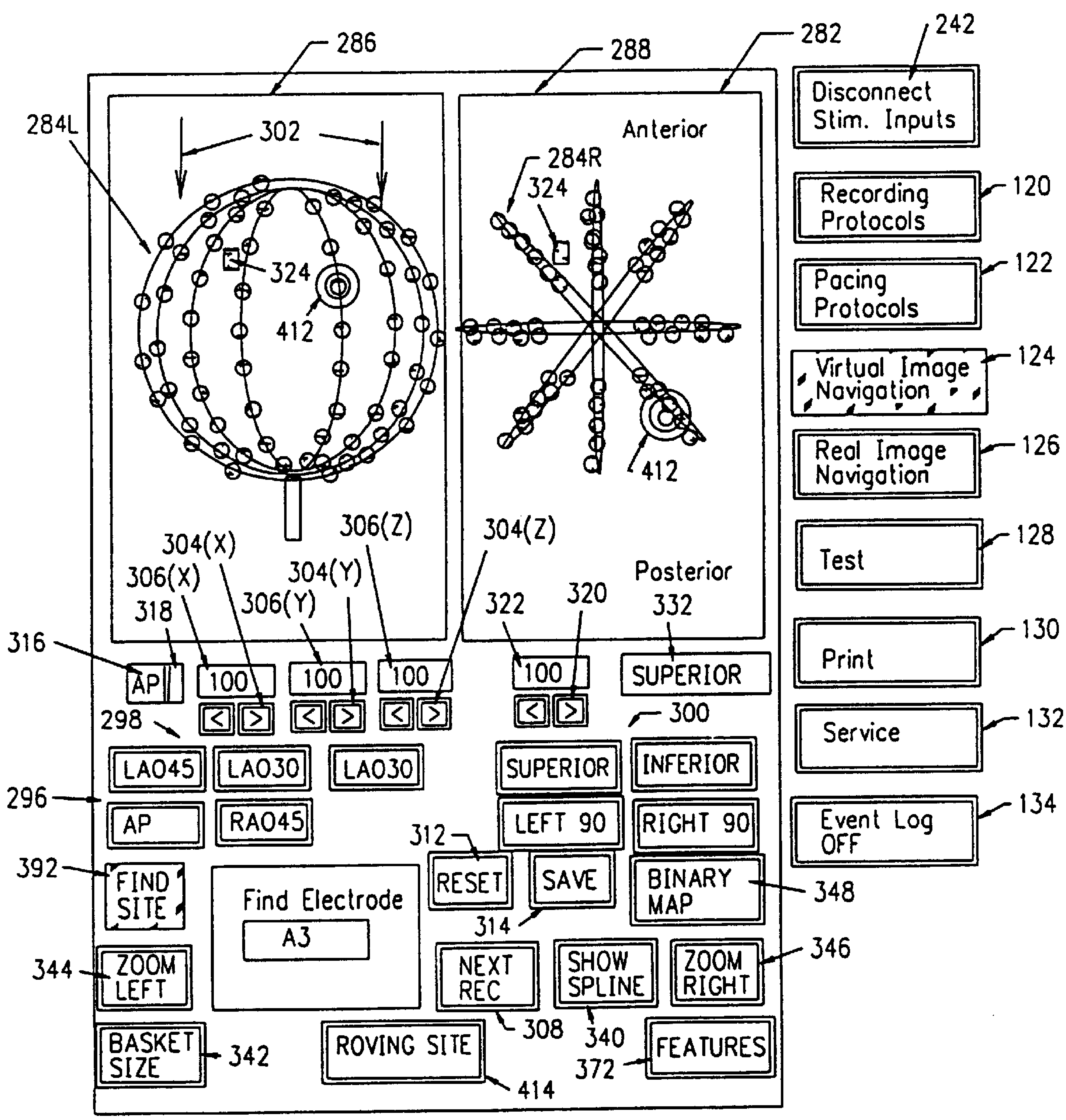

Disconnect Stim. Inputs
Recording Protocols
Pacing Protocols
Virtual Image Navigation
Real Image Navigation
Test
Print
Service
Event Log OFF
Anterior
Posterior
12:38P 1-6-98
Ablate Here
047
AP
100
SUPERIOR
LAO45
LAO30
LAO30
AP
RAO45
SUPERIOR
INFERIOR
LEFT 90
RIGHT 90
SAVE
BINARY MAP
FIND SITE
INSERT MARKER
ADD MARKERS
MOVE MARKERS
DEL MARKERS
CLOSE
ZOOM LEFT
SHOW PACE
SHOW SPLINE
ZOOM RIGHT
BASKET SIZE
FEATURES

FIG. 19



286
288
282
242
284L
302
Anterior
284R
324
324
412
412
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
304(X)
306(Z)
304(Z)
306(X)
304(Y)
Posterior
318
306(Y)
322
320
332
316
AP
100
100
100
100
SUPERIOR
298
300
LAO45
LAO30
LAO30
SUPERIOR
INFERIOR
296
AP
RAO45
LEFT 90
RIGHT 90
312
392
FIND SITE
Find Electrode
A3
RESET
SAVE
BINARY MAP
348
314
344
ZOOM LEFT
NEXT REC
SHOW SPLINE
ZOOM RIGHT
346
308
340
BASKET SIZE
342
ROVING SITE
372
FEATURES
414

FIG. 20

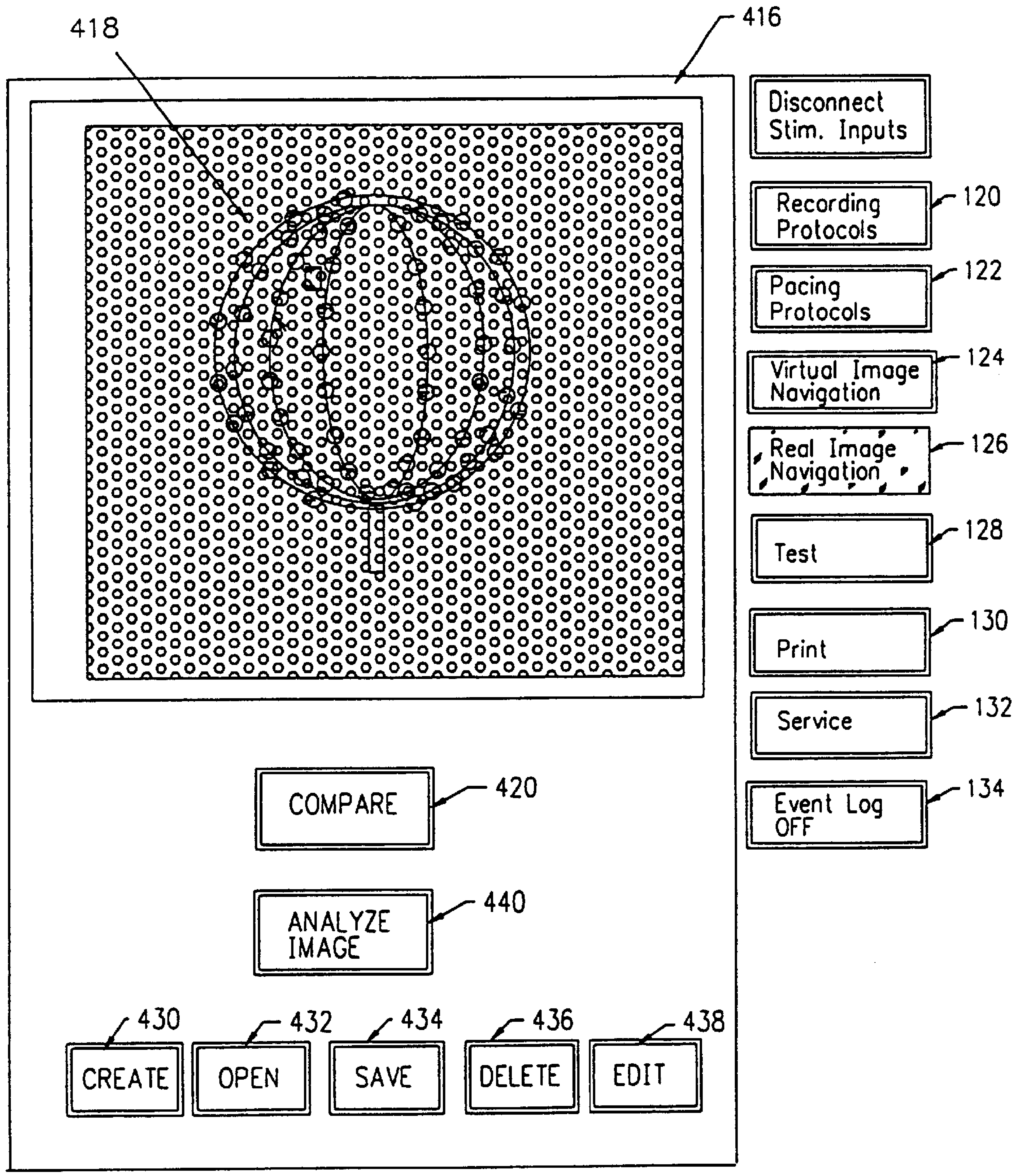

418
416
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
COMPARE
420
ANALYZE IMAGE
440
CREATE
430
OPEN
432
SAVE
434
DELETE
436
EDIT
438

FIG. 21

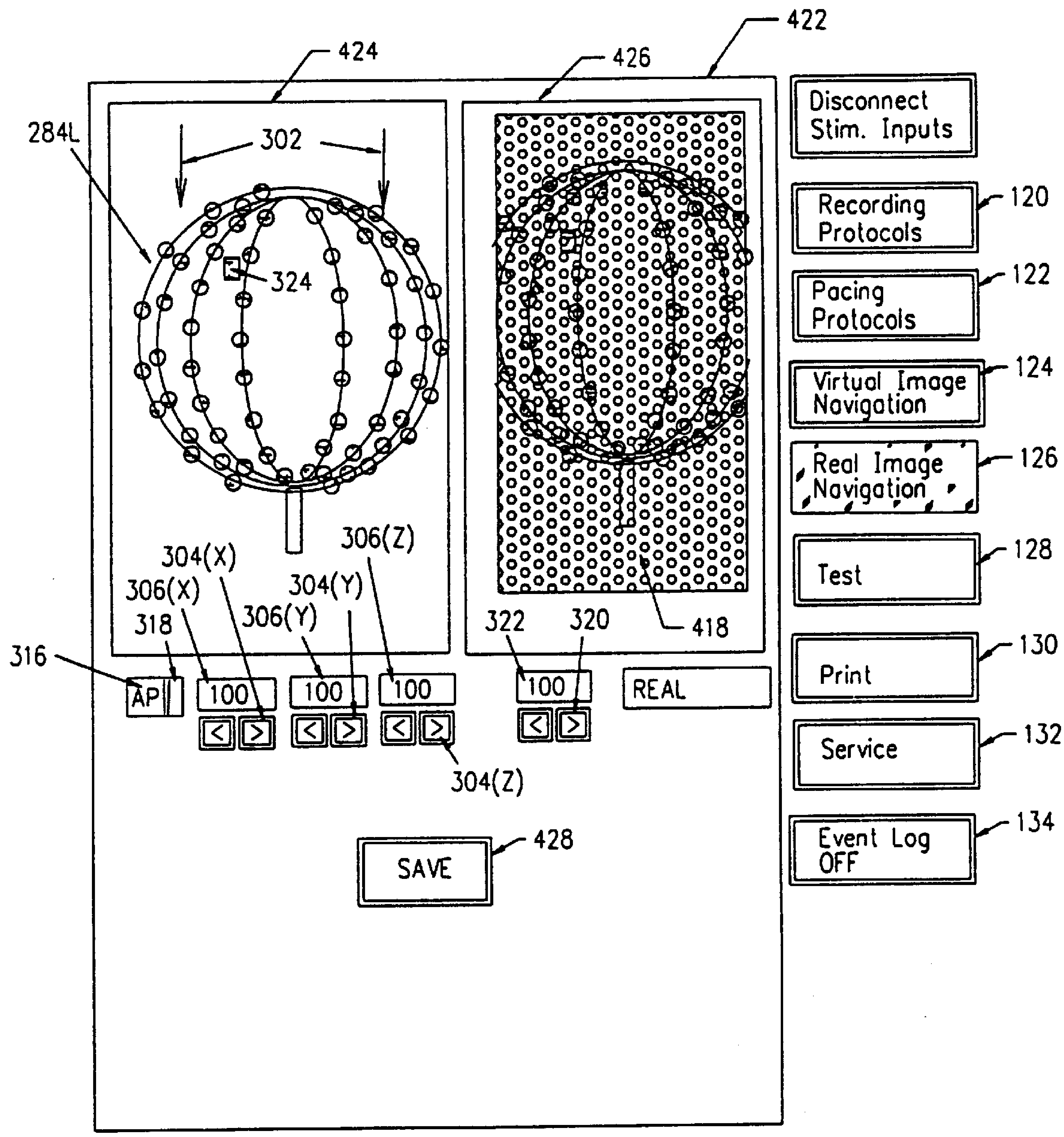
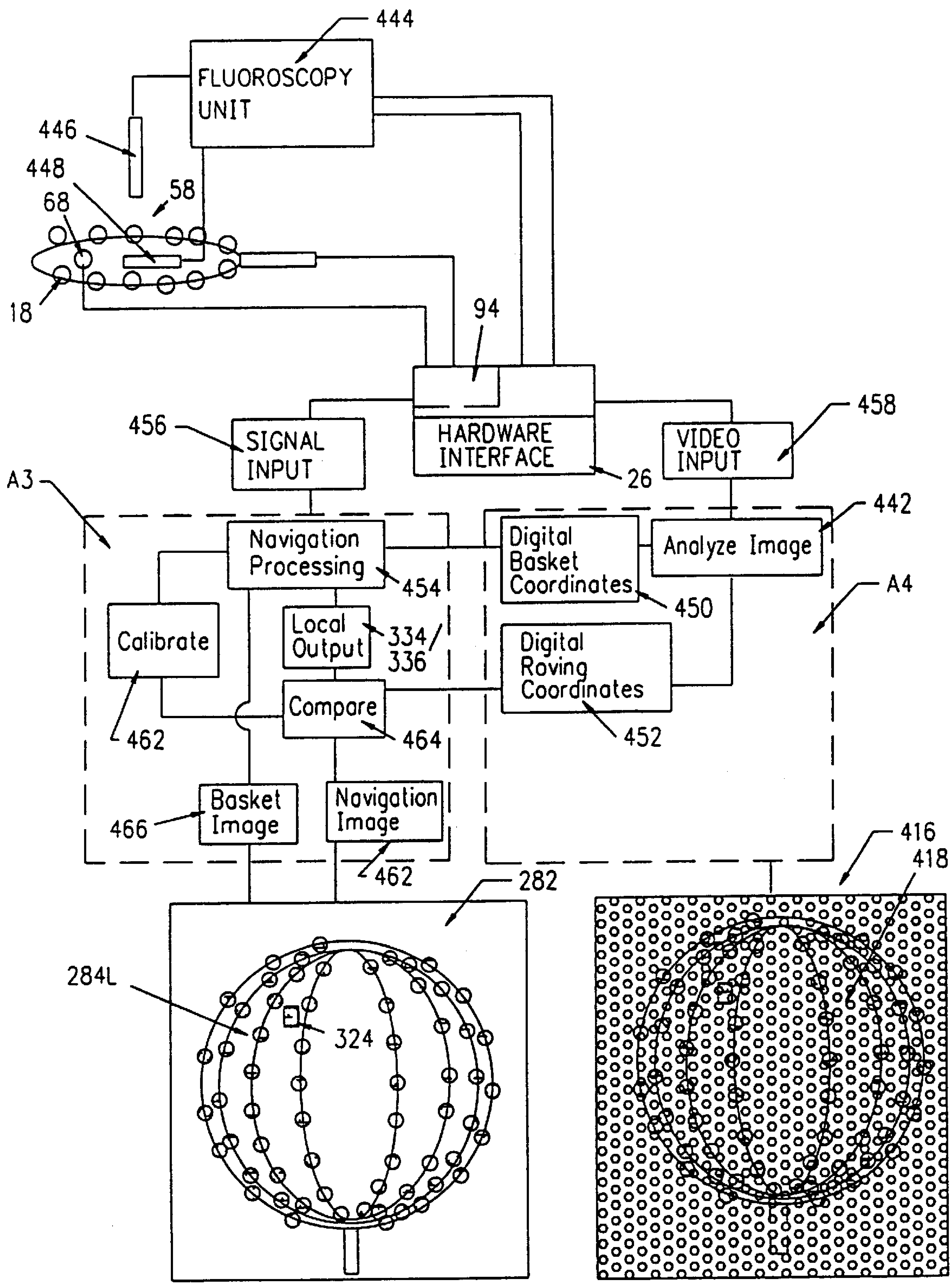

422
424
426
284L
302
324
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
304(X)
306(X)
306(Z)
304(Y)
306(Y)
318
316
AP
100
100
100
322
320
418
100
REAL
304(Z)
SAVE
428

FIG. 22



444
FLUOROSCOPY UNIT
446
448
68
58
18
94
HARDWARE INTERFACE
26
456
SIGNAL INPUT
VIDEO INPUT
458
A3
Navigation Processing
454
Digital Basket Coordinates
450
Analyze Image
442
A4
Calibrate
462
Local Output
334/
336
Compare
464
Digital Roving Coordinates
452
466
Basket Image
Navigation Image
462
282
416
418
284L
324

FIG. 23

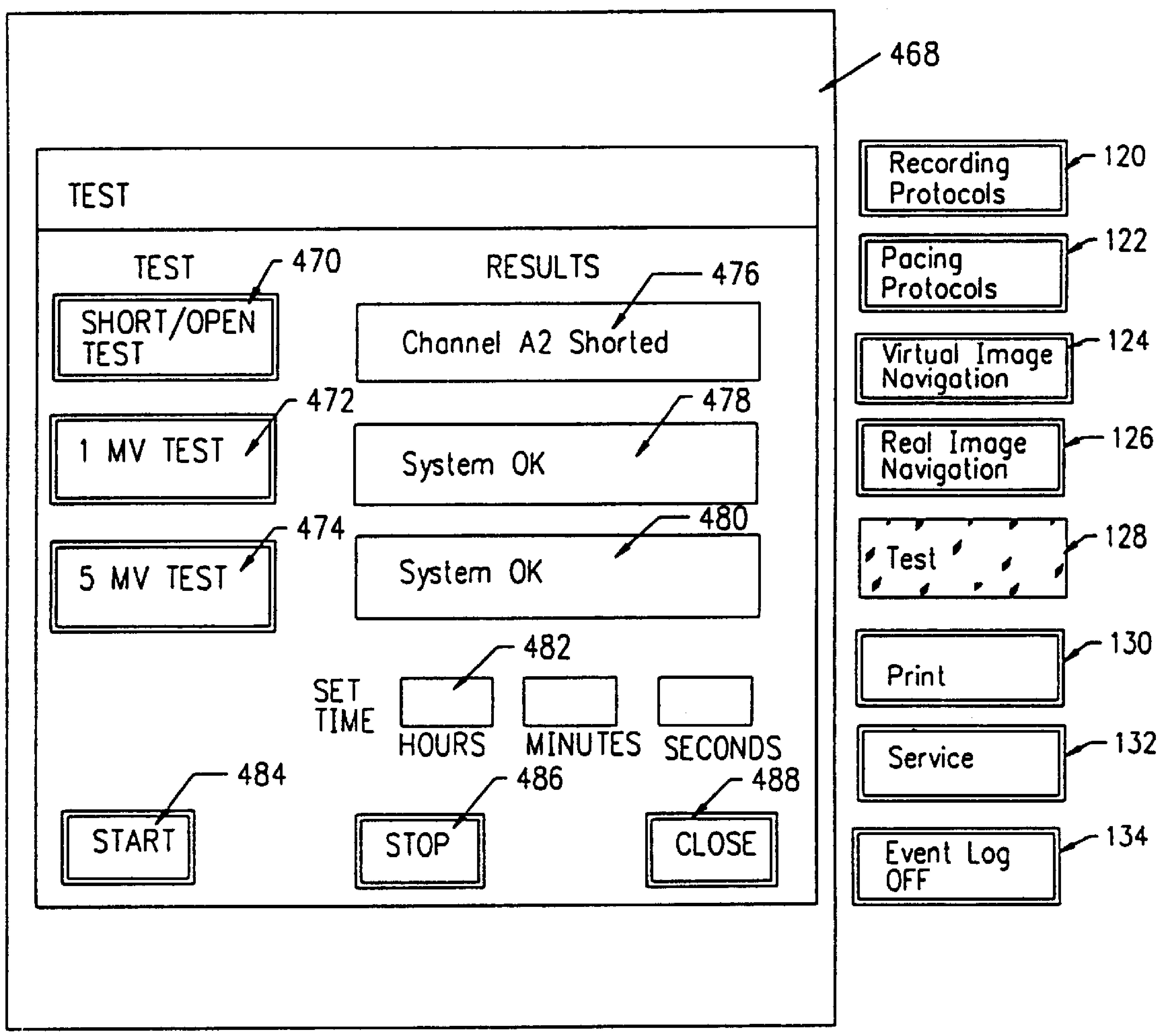

468
TEST
TEST
470
SHORT/OPEN TEST
RESULTS
476
Channel A2 Shorted
472
1 MV TEST
478
System OK
474
5 MV TEST
480
System OK
482
SET TIME
HOURS
MINUTES
SECONDS
484
486
488
START
STOP
CLOSE
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 24

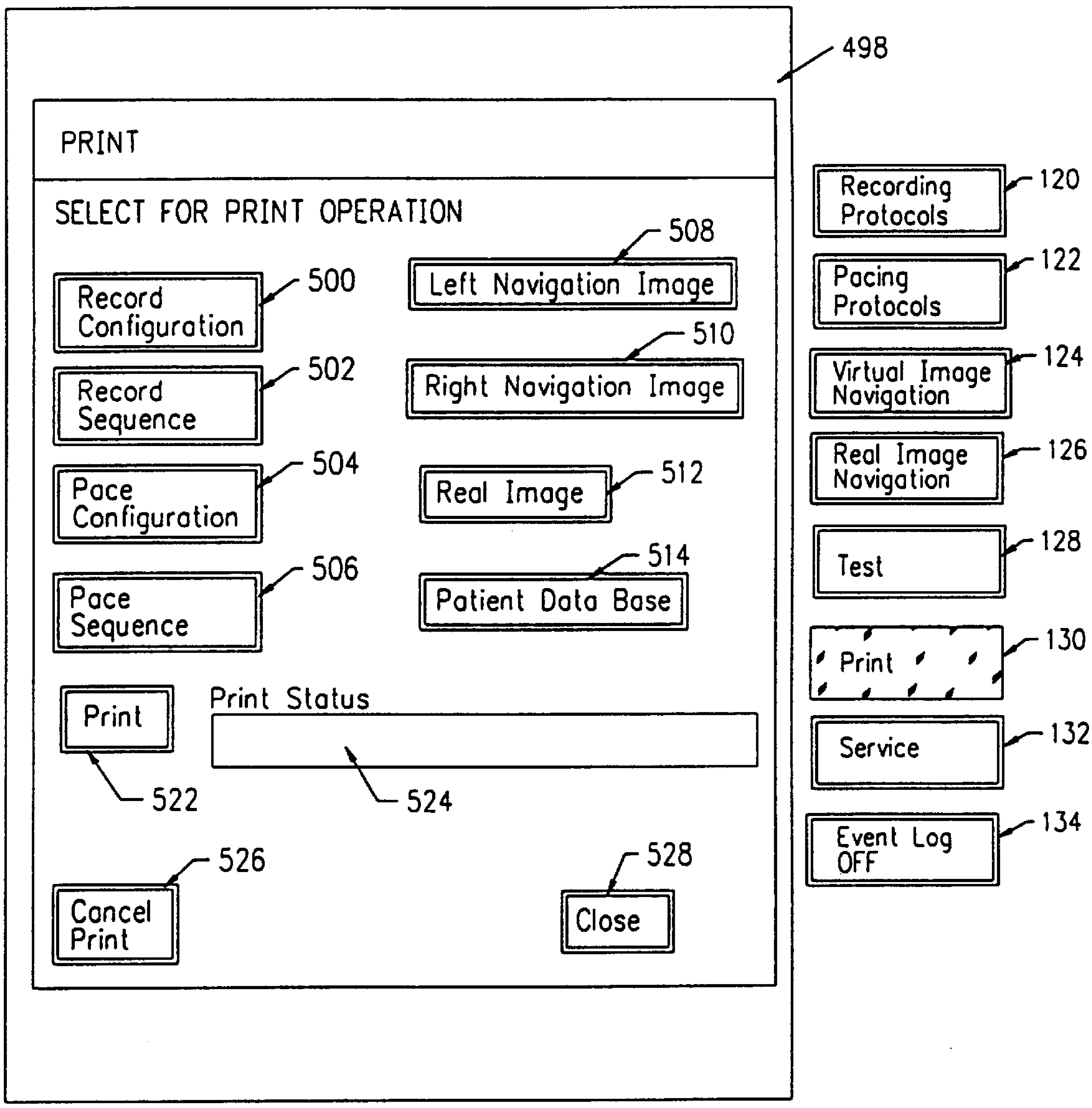
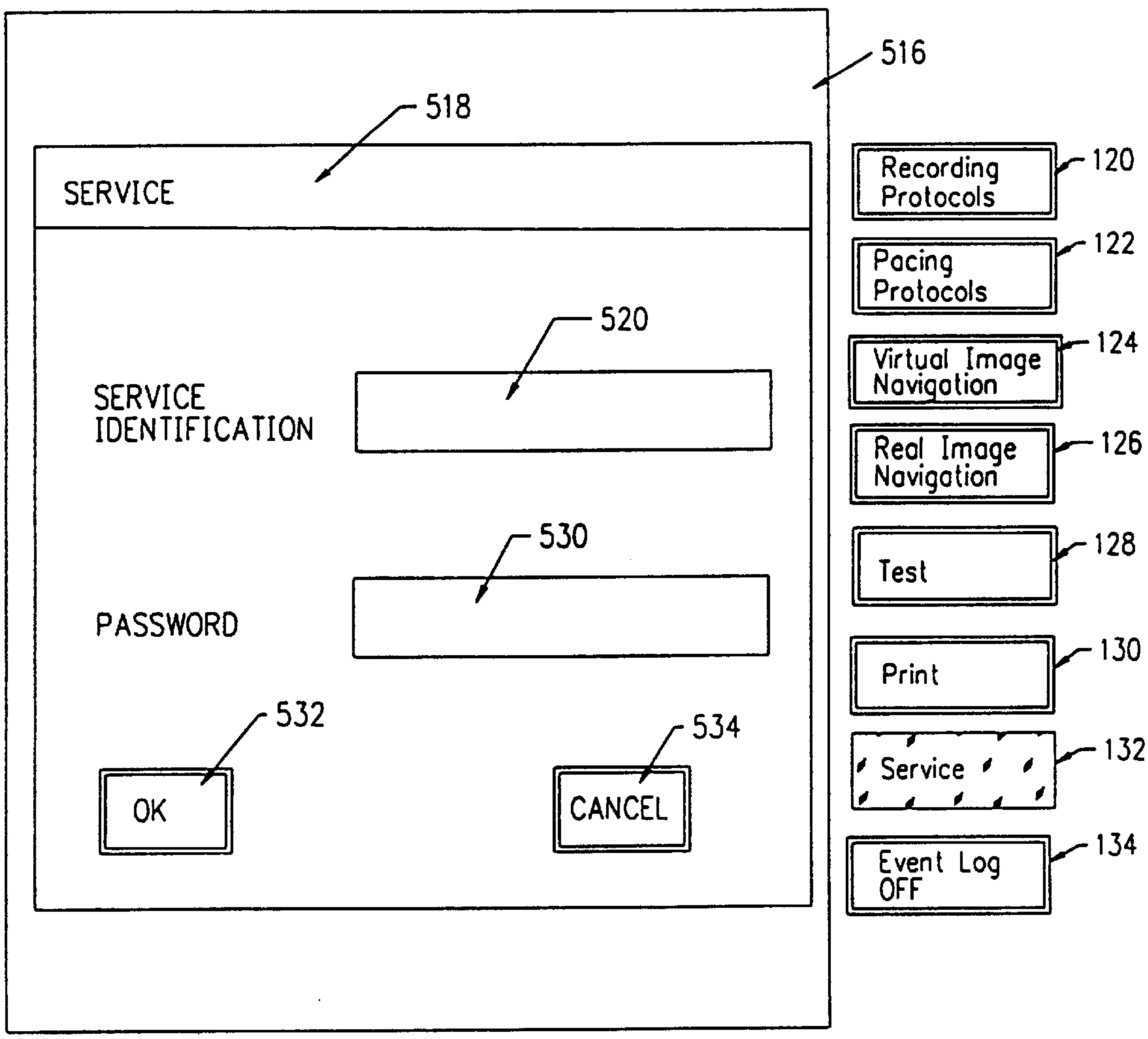

498
PRINT
SELECT FOR PRINT OPERATION
Record Configuration
500
Record Sequence
502
Pace Configuration
504
Pace Sequence
506
Left Navigation Image
508
Right Navigation Image
510
Real Image
512
Patient Data Base
514
Print
522
Print Status
524
Cancel Print
526
Close
528
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 25



516
518
SERVICE
520
SERVICE IDENTIFICATION
530
PASSWORD
532
OK
534
CANCEL
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 26

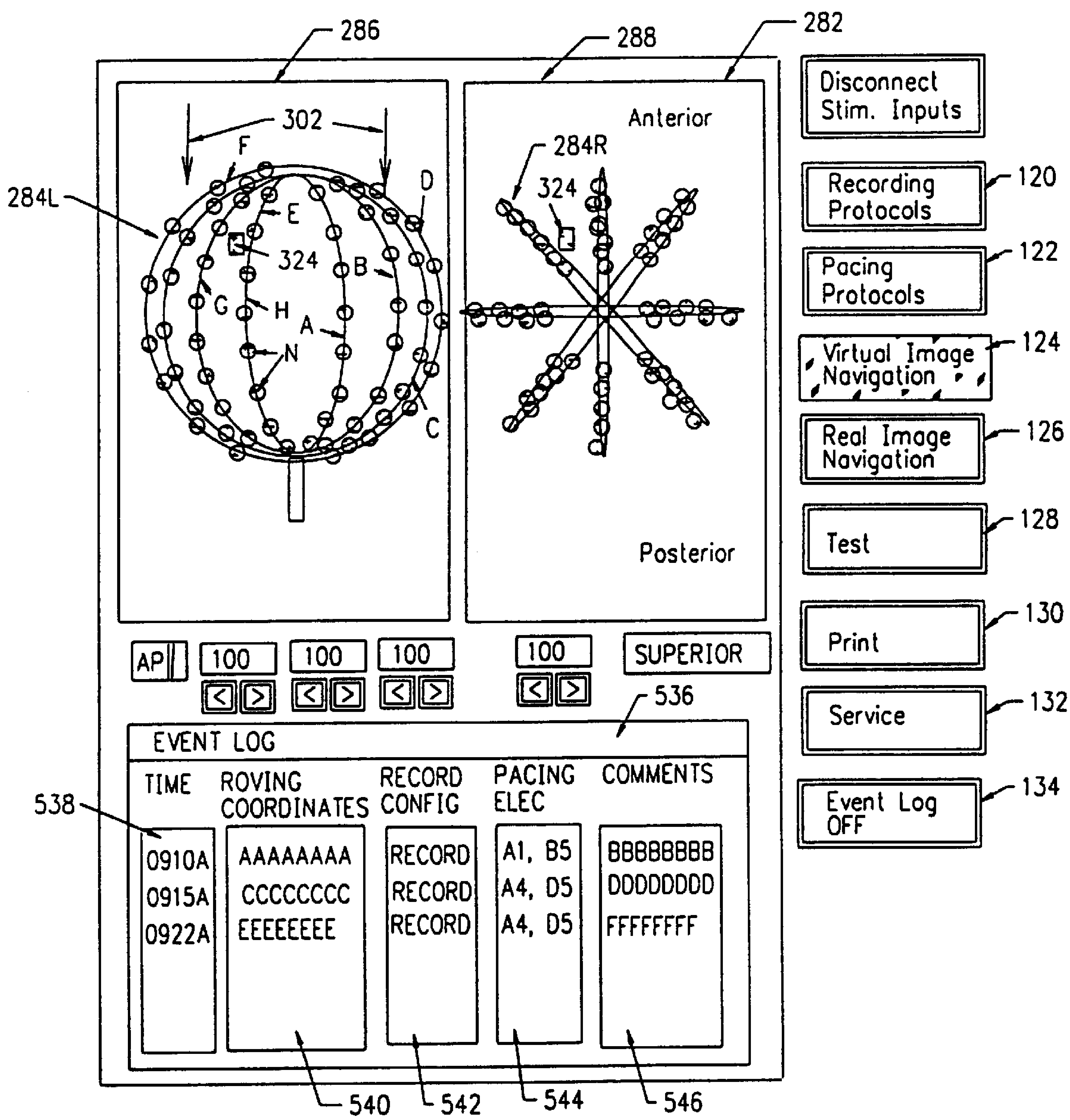

286
288
282
302
F
D
284L
E
324
B
G
H
A
N
C
Anterior
284R
324
Posterior
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
AP
100
100
100
100
SUPERIOR
536
EVENT LOG
538
TIME
ROVING COORDINATES
RECORD CONFIG
PACING ELEC
COMMENTS
0910A
0915A
0922A
AAAAAAAA
CCCCCCCC
EEEEEEEE
RECORD
RECORD
RECORD
A1, B5
A4, D5
A4, D5
BBBBBBBB
DDDDDDDD
FFFFFFFF
540
542
544
546

FIG. 27

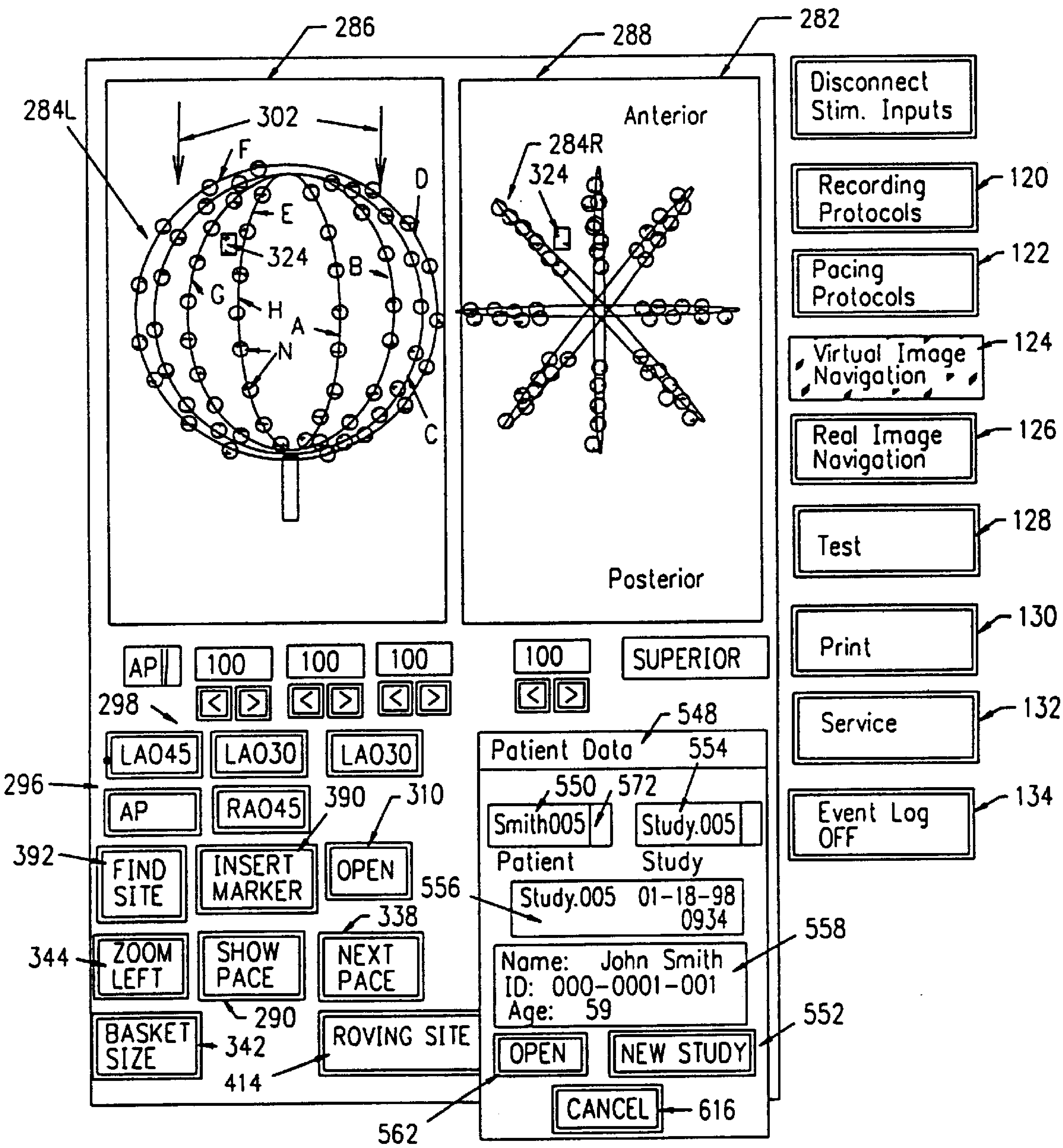

286
288
282
284L
302
F
D
E
324
B
G
H
A
N
C
Anterior
284R
324
Posterior
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
AP
100
100
100
100
SUPERIOR
298
548
Patient Data
554
LAO45
LAO30
LAO30
296
AP
RAO45
390
310
550
572
Smith005
Study.005
Patient
Study
392
FIND SITE
INSERT MARKER
OPEN
556
Study.005 01-18-98 0934
338
344
ZOOM LEFT
SHOW PACE
NEXT PACE
558
Name: John Smith
ID: 000-0001-001
Age: 59
290
BASKET SIZE
342
ROVING SITE
552
OPEN
NEW STUDY
414
CANCEL
616
562

FIG. 28

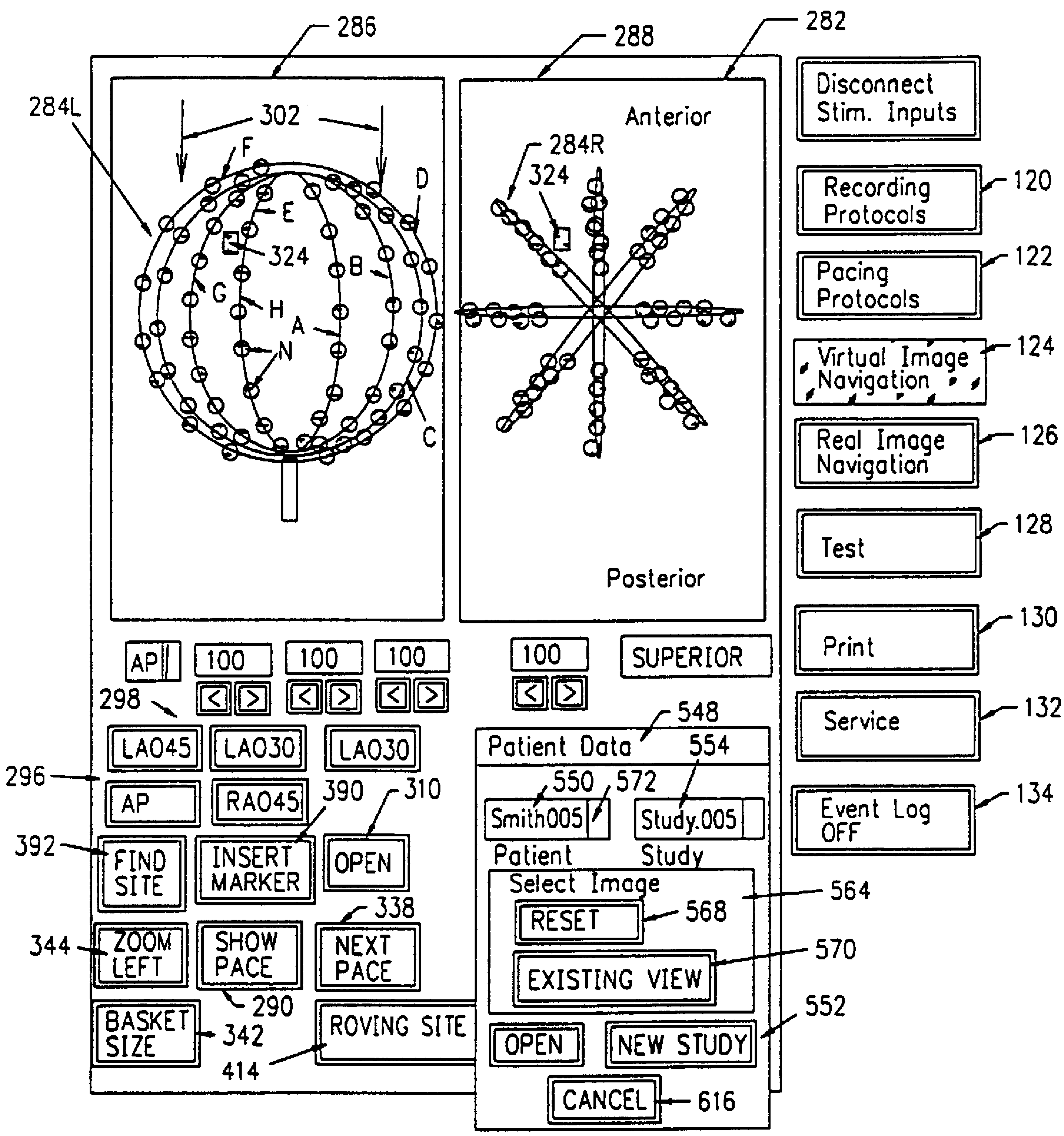

286
288
282
284L
302
F
D
E
324
B
G
H
A
N
C
Anterior
284R
324
Posterior
Disconnect Stim. Inputs
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134
AP
100
100
100
100
SUPERIOR
298
548
Patient Data
554
LAO45
LAO30
LAO30
296
AP
RAO45
390
310
550
572
Smith005
Study.005
Patient
Study
392
FIND SITE
INSERT MARKER
OPEN
Select Image
564
338
RESET
568
344
ZOOM LEFT
SHOW PACE
NEXT PACE
570
EXISTING VIEW
290
552
BASKET SIZE
342
ROVING SITE
OPEN
NEW STUDY
414
CANCEL
616

FIG. 29

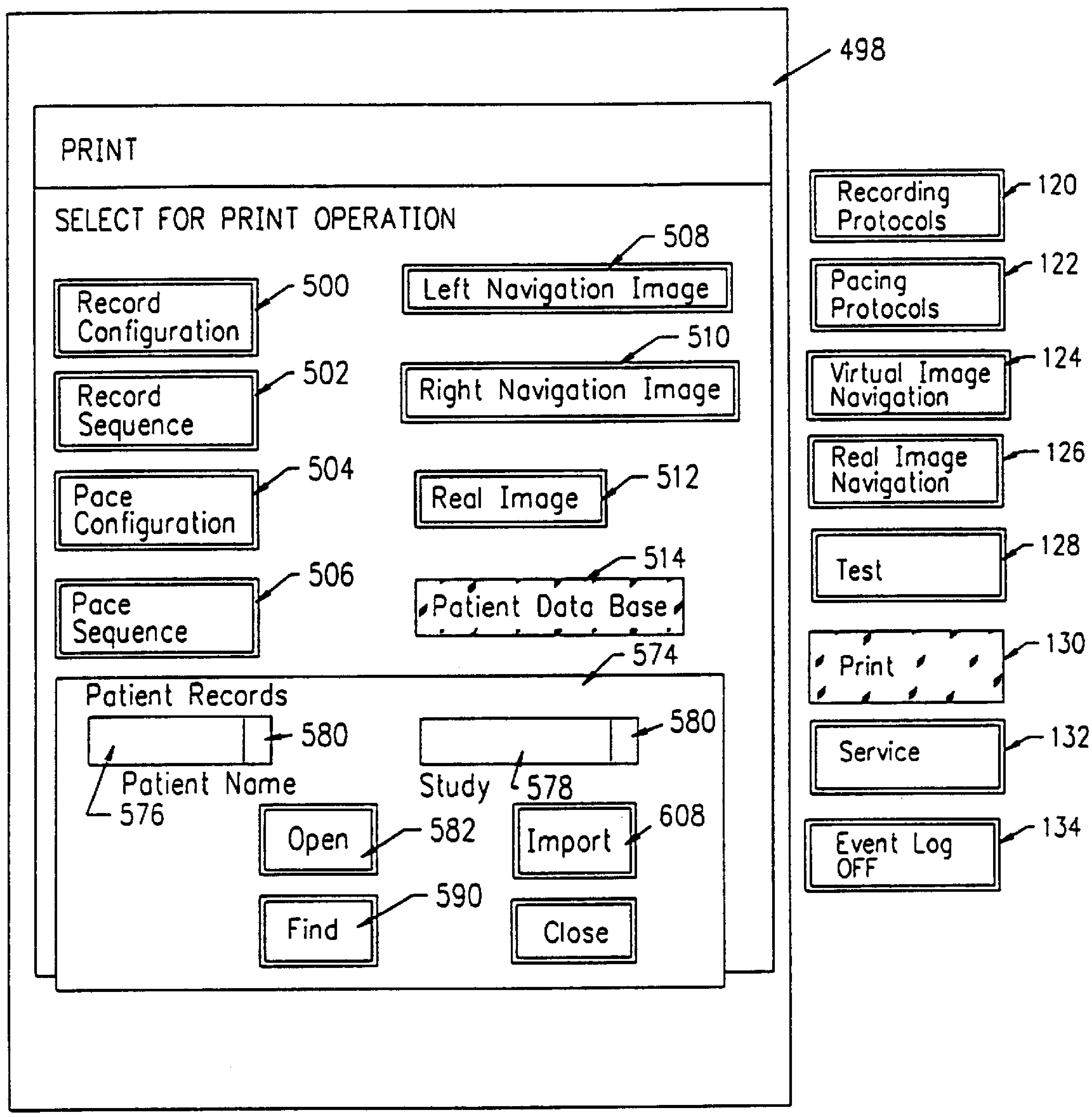
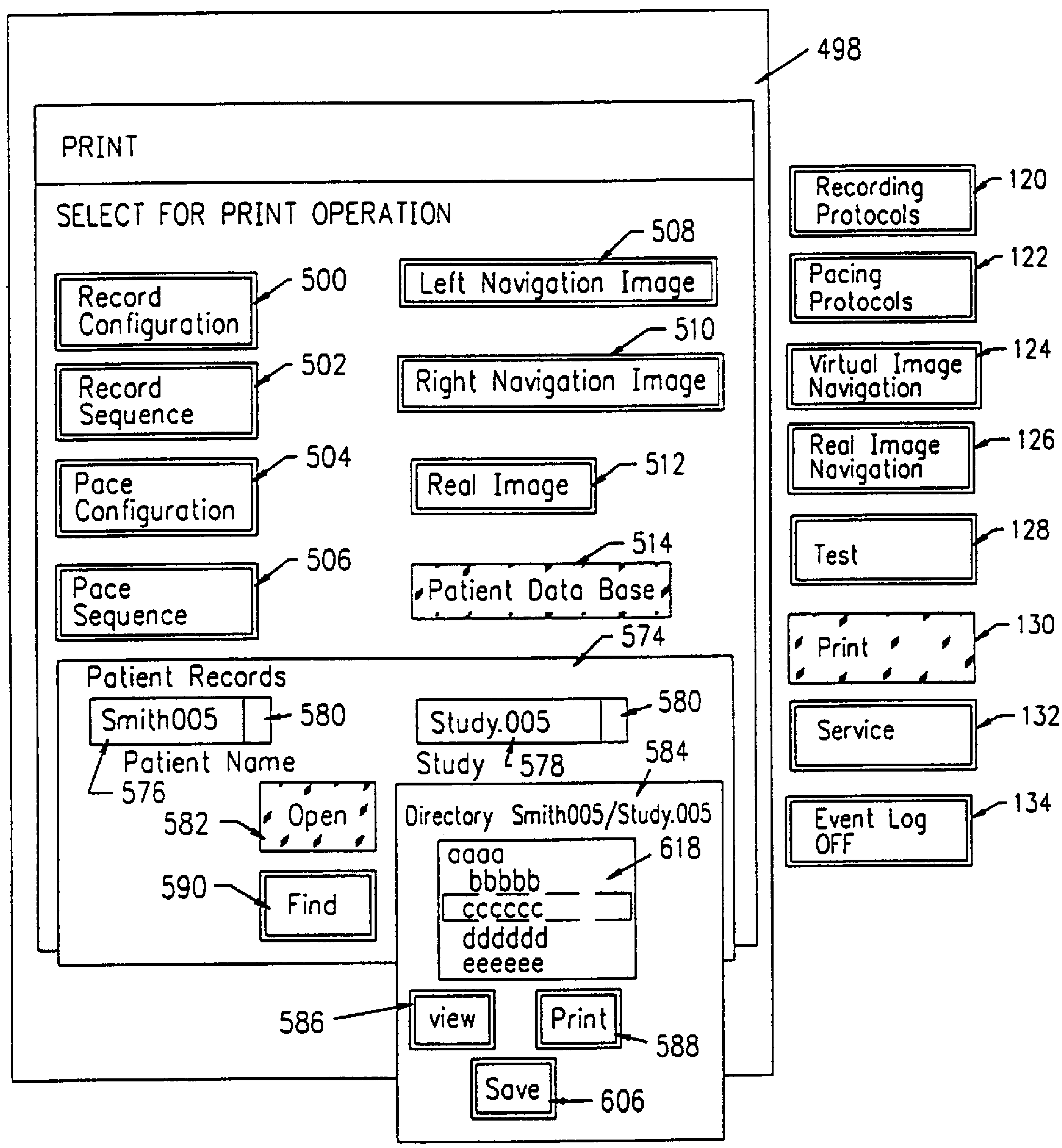
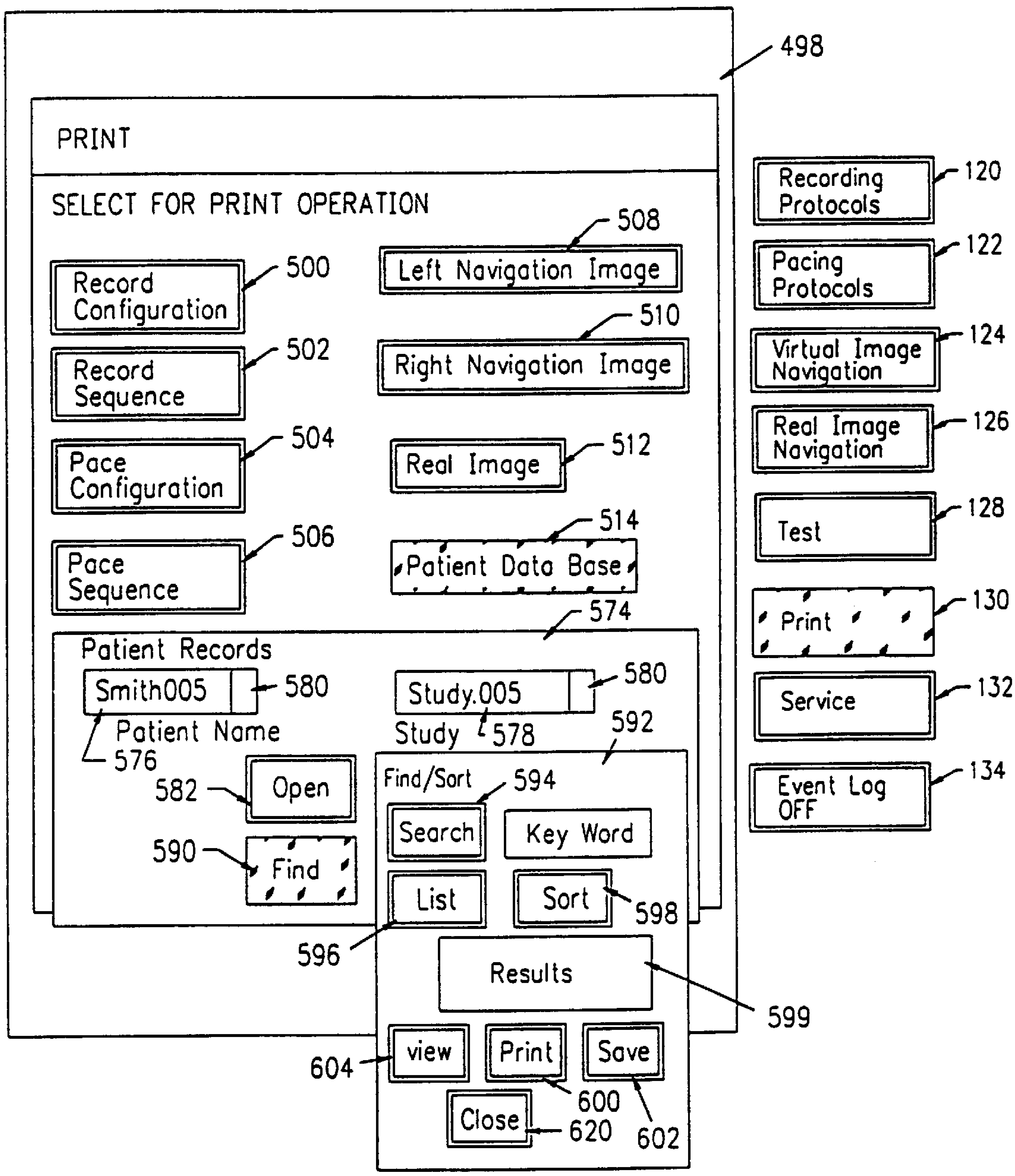

498
PRINT
SELECT FOR PRINT OPERATION
Record Configuration
500
Record Sequence
502
Pace Configuration
504
Pace Sequence
506
Left Navigation Image
508
Right Navigation Image
510
Real Image
512
Patient Data Base
514
Patient Records
574
580
Patient Name
576
Study
578
580
Open
582
Import
608
Find
590
Close
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 30



498
PRINT
SELECT FOR PRINT OPERATION
Record Configuration
500
Record Sequence
502
Pace Configuration
504
Pace Sequence
506
Left Navigation Image
508
Right Navigation Image
510
Real Image
512
Patient Data Base
514
574
Patient Records
Smith005
580
Patient Name
576
Study.005
580
Study
578
584
582
Open
590
Find
Directory Smith005/Study.005
aaaa
bbbbb
cccccc
dddddd
eeeeee
618
586
view
Print
588
Save
606
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 31



498
PRINT
SELECT FOR PRINT OPERATION
Record Configuration
500
Record Sequence
502
Pace Configuration
504
Pace Sequence
506
Left Navigation Image
508
Right Navigation Image
510
Real Image
512
Patient Data Base
514
574
Patient Records
Smith005
580
Patient Name
576
Study.005
580
Study
578
592
582
Open
590
Find
Find/Sort
594
Search
Key Word
List
Sort
598
596
Results
599
604
view
Print
Save
600
602
Close
620
Recording Protocols
120
Pacing Protocols
122
Virtual Image Navigation
124
Real Image Navigation
126
Test
128
Print
130
Service
132
Event Log OFF
134

FIG. 32

INTERACTIVE SYSTEMS AND METHODS FOR CONTROLLING THE USE OF DIAGNOSTIC OR THERAPEUTIC INSTRUMENTS IN INTERIOR BODY REGIONS

RELATED APPLICATION DATA

This application is a continuation of U.S. Ser. No. 09/048,629, filed on Mar. 26, 1998 now U.S. Pat. No. 6,106,460.

BACKGROUND OF THE INVENTION

This invention relates generally to systems for diagnosing and treating medical conditions using instruments deployed within a living body.

FIELD OF THE INVENTION

Multiple electrode arrays are used to diagnose or treat a variety of medical conditions.

For example, physicians use arrays of multiple electrodes to examine the propagation of electrical impulses in heart tissue to locate aberrant conductive pathways. The techniques used to analyze these pathways, commonly called "mapping," identify regions in the heart tissue, called foci, which can be ablated to treat the arrhythmia. When used for this purpose, the multiple electrode arrays are typically located in electrical contact with either epicardial or endocardial tissue. The multiple electrodes are coupled to an external cardiac stimulator, which applies electrical pacing signals through one or more electrodes at given frequencies, durations, or amplitudes to myocardial tissue, a process called "pacing." The multiple electrodes on the array are also typically coupled to signal processing equipment, called "recorders," which display the morphologies of the electrocardiograms or electrograms recorded during pacing. Sometimes, another roving electrode is deployed in association with the multiple electrode array, to pace the heart at various endocardial locations, a technique called "pace mapping." When it is desired to ablate myocardial tissue, an electrode coupled to a source of, e.g., radio frequency energy is deployed.

In conducting these diagnostic or therapeutic procedures, the physician must compare all paced electrocardiograms or electrograms to those previously recorded during an induced arrhythmia episode. The physician also must know the position of all deployed electrodes in order to interpret the data in a meaningful way. The physician also needs to be able to accurately maneuver and position the roving or ablation electrode, when used. For these reasons, these procedures required a considerable degree of skill and experience on the part of the attending medical personnel.

Conventional systems and methods designed to aid the physician in his difficult task became impractical and unwieldy as new technology provides more sophisticated arrays, have more electrodes arranged with increased density. With larger and more dense electrode arrays, the number of possible failure modes also increases. Conventional systems and methods cannot automatically and continuously monitor the status of the more sophisticated arrays, to warn the physician in the event of an opened or shorted electrode condition or other malfunction.

Thus, there is a need for improved systems and methods for manipulating and monitoring the use of multiple electrode arrays, as well as systems and methods for processing, monitoring, and interpreting data from multiple electrode arrays in an efficient, organized manner.

SUMMARY OF THE INVENTION

One aspect of the invention provides an interface for association with a structure which, in use, is deployed in an interior body region of a patient. The structure includes an operative element coupled to a controller, which establishes an operating condition for the operative element to perform a diagnostic or therapeutic procedure in the interior body region. According to this aspect of the invention, the interface comprises a display screen and an interface manager coupled to controller and the display screen. The interface manager includes a first function to generate a first display comprising an image of the structure at least partially while the operative element performs the procedure. The interface manager also includes a second function to generate a second display comprising one or more data fields reflecting the operating condition of the controller. The interface manager further includes a third function to enable selection of the first display or the second display for viewing on the display screen.

This aspect of the invention also provides a method, by which the structure can be deployed in the interior body region while an operator selects the first display or the second display for viewing on a display screen.

Another aspect of the invention provides systems and methods for examining myocardial tissue. The systems and methods deploy an electrode structure in contact with myocardial tissue. The systems and methods generate a first display comprising an image of the electrode structure, while also generating a second display comprising one or more data fields reflecting an operating condition of the electrode structure. The systems and methods cause the electrode structure to either pace myocardial tissue, or record electric events in myocardial tissue, or both, while selecting the first display or the second display for viewing on a display screen.

Other features and advantages of the inventions are set forth in the following Description and Drawings, as well as in the appended Claims.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a schematic view of a system, which couples several individually controlled diagnostic or therapeutic instruments to a main processing unit through an instrument interface and which includes a graphical user interface (GUI);

FIG. **2** is a schematic view of the representative instruments, including a multiple electrode basket, a roving electrode, and a roving imaging device, which are coupled to individual controllers via the instrument interface;

FIG. **3** is a schematic view of the instrument interface;

FIG. **4** is a depiction of the start-up screen of the GUI;

FIG. **5** is a depiction of the record protocols-configuration screen of the GUI;

FIG. **6** is a depiction of the record protocols-sequence screen of the GUI;

FIG. **7** is a depiction of the pace protocols-configuration screen of the GUI;

FIG. **8** is a depiction of the pace protocols-sequence screen of the GUI;

FIG. **9** is a depiction of the virtual image navigation screen of the GUI;

FIG. **10** is an enlarged view of the idealized image of the multiple electrode basket displayed by the virtual image navigation screen of the GUI;

FIG. **11** is a depiction of the virtual image navigation screen of the GUI, with the Binary Map dialog box displayed;

FIG. **12** is a depiction of the binary map dialog box with the Create Map control button selected;

FIG. **13** is a depiction of the virtual image navigation screen of the GUI, with the Anatomic Features dialog boxes displayed;

FIG. **14** is a schematic view showing the creation of proximity-indicating output for display by the virtual image navigation screen of the GUI;

FIG. **15** is an enlarged view of an idealized image displayed by the virtual image navigation screen of the GUI, with the Sensitivity Adj dialog box displayed for adjusting sensitivity of the proximity-indicating output;

FIG. **16** is an enlarged view of an idealized image displayed by the virtual image navigation screen of the GUI, showing the interpolation of proximity-indicating output;

FIG. **17** is a schematic view showing the creation of location output based upon spacial variations in electrical potentials, for display by the virtual image navigation screen of the GUI;

FIG. **18** is a schematic view showing the creation of location output based upon differential waveform analysis, for display by the virtual image navigation screen of the GUI;

FIG. **19** is a depiction of the virtual image navigation screen of the GUI, with the Markers dialog box displayed;

FIG. **20** is a depiction of the virtual image navigation screen of the GUI, with the Find Site dialog box displayed;

FIG. **21** is a depiction of the real image navigation screen of the GUI;

FIG. **22** is a depiction of the real image navigation screen of the GUI, with the compare image function enabled;

FIG. **23** is a schematic showing an implementation of the analyze image function;

FIG. **24** is a depiction of the test screen of the GUI;

FIG. **25** is a depiction of the print screen of the GUI;

FIG. **26** is a depiction of the service screen of the GUI;

FIG. **27** is a depiction of the virtual image navigation screen of the GUI, with the Event Log control button function toggled on to display the Event Log;

FIG. **28** is a depiction of the virtual image navigation screen of the GUI, with the Patient Data Base function enabled and the Patient Data dialog box opened for data input at the outset of a new study;

FIG. **29** is a depiction of the virtual image navigation screen of the GUI, with the Patient Data Base function enabled and the Select Image dialog box opened for data input;

FIG. **30** is a depiction of the print screen of the GUI, with the Patient Data Base control button selected to open the Patient Records dialog box;

FIG. **31** is a depiction of the print screen of the GUI, with the Patient Data Base control button selected and the Directory dialog box opened; and

FIG. **32** is a depiction of the print screen of the GUI, with the Patient Data Base control button selected and the Find/Sort dialog box opened.

The invention may be embodied in several forms without departing from its spirit or essential characteristics. The scope of the invention is defined in the appended claims, rather than in the specific description preceding them. All embodiments that fall within the meaning and range of equivalency of the claims are therefore intended to be embraced by the claims.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

I. SYSTEM OVERVIEW

FIG. **1** shows a system **10** for diagnosing, treating or otherwise administering health care to a patient.

The system **10** includes various diagnostic or therapeutic instruments. For the purpose of illustration, FIG. **1** shows three instruments **12**, **14**, and **16**.

In the illustrated embodiment, the instrument **12** comprises an array of multiple electrodes **18**. In the illustrated embodiment, the instruments **14** and **16** each comprises an operative element usable for some diagnostic or therapeutic purpose.

For example, one of the operative elements **14** or **16** can comprise a device for imaging body tissue, such as an ultrasound transducer or an array of ultrasound transducers, or an optic fiber element, or a CT or MRI scanner. Alternatively, one of the operative elements **14** or **16** can comprise a device to deliver a drug or therapeutic material to body tissue. Still alternatively, one of the operative elements **14** or **16** can comprise a device, e.g., an electrode, for sensing a physiological characteristic in tissue, such as electrical activity in heart tissue, or for transmitting energy to stimulate or ablate tissue.

When deployed in the body, the operative elements **14** and **16** can be readily moved relative to the multiple electrode array **12**. For this reason, the instruments **14** and **16** will also each sometimes be called a "roving instrument."

The system **10** includes one or more instrument controllers (designated **20**, **22**, and **24**). In use, the controllers **20**, **22**, and **24** condition an associated instrument **12**, **14**, and **16** to perform its desired diagnostic or therapeutic functions. The functions depend upon the medical objectives of the system **10**. Representative specific examples will be described later.

To aid in coordinating signal and data flow among the controllers **20**, **22**, and **24** and their linked instruments, the system **10** includes an instrument manager or interface **26**. The interface **26** couples the instrument controllers **20**, **22**, and **24** to their respective instruments **12**, **14**, and **16**, establishing electrical flow paths, which process the various diagnostic or therapeutic data and signals in an organized and efficient fashion. Generally speaking, the interface **26** serves as a master switching unit, which governs the connections linking the instrument controllers **20**, **22**, and **24** to the individual instruments **12**, **14**, and **16**.

The interface **26** can comprise an integrated module, or an assembly of discrete components. Further details of a representative embodiment for the interface **26** will described later.

The system **10** also includes a main processing unit (MPU) **28**. In the illustrated embodiment, the MPU **28** comprises a Pentium™ type microprocessor, although other types of conventional microprocessors can be used.

The MPU **28** includes an input/output (I/O) device **30**, which controls and monitors signal and data flow to and from the MPU **30**. The I/O device **30** can comprise, e.g., one or more parallel port links and one or more conventional Ser. RS-232C port links or Ethernet™ communication links.

The I/O device **30** is coupled to a data storage module or hard drive **32**, as well as to the instrument interface **26** and a printer **34**.

The system **10** also includes an operator interface module **36**, which is coupled to the I/O device **30**. In the illustrated embodiment, the operator interface **36** includes a graphics display monitor **38**, a keyboard input **40**, and a pointing input device **42**, such as a mouse or trackball. The graphics display monitor **38** can also provide for touch screen input.

The system **10** includes an operating system **44** for the MPU **28**. In the illustrated embodiment, the operating system **44** resides as process software on the hard drive **32**, which is down loaded to the MPU **28** during system initialization and startup. For example, the operating system **44** can comprise a Microsoft WINDOWS® 3.1, WINDOWS 95® or NT operating system. Alternatively, the operating system **44** can reside as process software in EPROM's in the MPU **28**.

In the illustrated embodiment, the operating system **44** executes through the operator interface **36** a graphical user interface, or GUI **46**, the details of which will be described later. Preferably, the GUI **46** is configured to operate on a WINDOWS® compatible laptop or desktop computer. The GUI **46** can be realized, e.g., as a "C" language program implemented using the MS WINDOWS™ application and the standard WINDOWS 32 API controls, e.g., as provided by the WINDOWS™ Development Kit, along with conventional graphics software disclosed in public literature.

The MPU **28**, hard drive **32**, and the components of the operator interface **36** can be implemented in a conventional lap top or desktop computer, which serves as a host for the operating system **44** and GUI **46**. Other computer system forms can, of course, be used, e.g., using a server to host the operating system **44** and GUI **46** for a network of workstations, each of which comprises an operator interface **36**.

In whatever form, the operating system **44** administers the activation of a library **48** of control applications, which are designated, for purpose of illustration, as **A1** to **A7** in FIG. **1**. In the illustrated embodiment, the control applications **A1** to **A7** all reside in storage **54** as process software on the hard drive **32** and are down loaded and run based upon operator input through the GUI **46**. Alternatively, all or some of the control applications **A1** to **A7** can reside as process software in EPROM's in the MPU **28**, which can likewise be called and run through the GUI **46**.

Each control application **A1** to **A7** prescribes procedures for carrying out given functional tasks using the system **10** in a predetermined way of course, the number and functions of the applications **A1** to **A7** can vary.

In the illustrated and preferred embodiment, the library **48** includes one or more clinical procedure applications, which are designated **A1** and **A2** in FIG. **1**. Each procedure application **A1** and **A2** contains the steps to carry out a prescribed clinical procedure using the system **10**. When run by the operating system **44**, each procedure application **A1** and **A2** generates prescribed command signals, which the I/O device **30** distributes via the instrument interface **26** to condition the instrument controllers **20**, **22**, and **24** to perform a desired task using the instruments **12**, **14**, and **16**. The I/O device **26** also receives data from the instrument controllers **20**, **22**, and **24** via the instrument interface **26** for processing by procedure application **A1** or **A2** being run. The GUI **46** presents to the operator, in a graphical format, various outputs generated by the procedure application **A1** or **A2** run by the operating system **44** and allows the user to alter or modify specified processing parameters in real time. Further details of specific representative procedure applications **A1** and **A2** will be described in greater detail later.

In the illustrated and preferred embodiment, the library **48** also includes one or more specialized navigation applications **A3** and **A4**. The navigation applications **A3** and **A4**, when run by the operating system **44**, allow the operator to visualize on the GUI **46** the orientation of the multiple electrode array **12** and roving instruments **14** and **16** when deployed in an interior body region. The navigation applications **A3** and **A4** thereby assist the operator in manipulating and positioning these instruments to achieve the diagnostic or therapeutic results desired. In the illustrated embodiment, one navigation application **A3** constructs an ideal or virtual image of the deployed array **12** and the roving instruments **14**, and **16**, while the other navigation application **A4** displays an actual, realtime image of these instruments **12**, **14**, and **16**. One or both of the navigation applications **A3** and **A4** can also display in graphical form on the GUI **44** information to aid the operator in interpreting data acquired by the multiple electrode array **12** and roving instruments **14** and **16** when deployed in an interior body region.

In the illustrated and preferred embodiment, the library **48** also includes one or more utility applications **A5** to **A7**. The utility applications **A5** to **A7** carry out, e.g., system testing, system servicing, printing, and other system support functions affecting the all applications. Further details of representative utility applications **A5** to **A7** will be described in greater detail later.

The operating system **44** also includes one or more speciality functions (designated F1 and F2 in FIG. **1**), which run in the background during execution of the various applications **A1** to **A7**. For example, one function F1 can serve to establish and maintain an event log **50**, stored in the hard drive **32**, which keeps time track of specified important system events as they occur during the course of a procedure. Another function F2 can serve to enable the operator, using the GUI **44**, to down load patient specific information generated by the various applications **A1** to **A7** to the hard drive **32** as data base items, for storage, processing, and retrieval, thereby making possible the establishment and maintenance of a patient data base **52** for the system **10**.

As described, the system **10** is well adapted for use inside body lumens, chambers or cavities for either diagnostic or therapeutic purposes. For this reason, the system **10** will be described in the context of its use within a living body.

The system **10** particularly lends itself to catheter-based procedures, where access to the interior body region is obtained, for example, through the vascular system or alimentary canal. Nevertheless, the system **10** can also be used in association with systems and methods that are not necessarily catheter-based, e.g., laser delivery devices, atherectomy devices, transmyocardial revascularization (TMR), percutaneous myocardial revascularization (PMR), or hand held surgical tools.

For example, the system **10** can be used during the diagnosis and treatment of arrhythmia conditions within the heart, such as ventricular tachycardia or atrial fibrillation. The system **10** also can be used during the diagnosis or treatment of intravascular ailments, in association, for example, with angioplasty or atherectomy techniques. The system **10** also can be used during the diagnosis or treatment of ailments in the gastrointestinal tract, the prostrate, brain, gall bladder, uterus, and other regions of the body.

For the purpose of illustration, representative components of the system **10** will be described in the context of the diagnosis and treatment of abnormal cardiac conditions. In this environment, the multiple electrode array **12** and roving instruments **14** and **16** are deployable within or near a heart chamber, typically in one of the ventricles.

A. Operating Instruments

The structure of the array of multiple electrodes **18** carried by the first instrument **12** can vary. In the illustrated embodiment (see FIG. **2**), the instrument **12** comprises a composite, three-dimensional basket structure **58** that is carried at the distal end of a catheter tube **56** for introduction into the targeted heart chamber. The basket structure includes eight spaced apart spline elements (alphabetically designated A to H in FIG. **2**) assembled together by a distal hub **60** and a proximal base **62**. Each spline A to H, in turn, carries eight electrodes **18**, which are numerically designated on each spline from the most proximal to the most distal electrode as **1** to **8** in FIG. **2**. The basket structure **58** thus supports a total of sixty-four electrodes **18**, which FIG. **2** identifies alphanumerically by spline and electrode order, e.g., (A,8), which identifies the most distal electrode on spline A. Of course, a greater or lesser number of spline elements and/or electrodes **18** can be present.

Each spline element A to H preferably comprises a flexible body made from resilient, inert wire or plastic. Elastic memory material such as nickel titanium (commercially available as NITINOL™ material) can be used. Resilient injection molded plastic or stainless steel can also be used. Each spline element A to H is preferably preformed with a convex bias, creating a normally open threedimensional basket structure.

The basket structure **58** is deployed in the heart by advancement through a conventional guide sheath (not shown) snaked through the vasculature. The guide sheath compresses and collapses the structure **58**. Retraction of the guide sheath allows the structure **58** to spring open into the three-dimensional shape shown in FIG. **2**. Further details of the structure and deployment of the multiple electrode structure can be found in U.S. Pat. No. 5,647,870, which is incorporated herein by reference.

Each of the electrodes **18** is electrically connected to an individual conductor in a multiple conductor cable **64** (see FIG. **1** also). The cable **64** terminates in one or more connectors, through which electrical connection can be made to the individual conductors and, hence, to the individual electrodes. The connectors are coupled to the instrument interface **26**.

The instrument **12** need not be configured as a basket **58**. For example, the array can take the form of an elongated electrode array, which can be straight, curved, or formed into a loop. For another example, a three-dimensional structure can be formed carrying dual outer and inner arrays of electrodes.

In the illustrated embodiment (see FIG. **2**), the first roving instrument **14** is also carried at the distal end of a catheter tube **66** for deployment and manipulation in the body. In the illustrated embodiment representative for the system **10**, the instrument **14** comprises an electrode **68** intended, in use, to sense electrical activity in heart tissue, as well as to transmit energy to stimulate or ablate tissue. The electrode **68** is electrically connected by a cable **70** to the instrument interface **26**.

The second roving instrument **16** comprises an imaging device **72**. The imaging device **72** operates using a selected visualizing technique, e.g., fluoroscopy, ultrasound, CT, or MRI, to create a real-time image of a body region. A cable **76** conveys signals from the imaging device **72** to the instrument interface **26**.

B. Instrument Controllers

In the representative embodiment (see FIG. **2**), the instrument controller **20** comprises at least one external cardiac stimulator. The cardiac stimulator **20** hosts a selection of diagnostic procedures, which generates electrical pulses of various duration, number, and cycles. The pulses stimulate or pace myocardial tissue, so that resultant electrical activity can be mapped.

A stimulator **20** of the type is of the type currently used in electrophysiology labs and can be commercially purchased, e.g., from Medtronic or Bloom, and. The system **10** can include additional stimulators, if desired. When multiple stimulators are present, the interface **26** can quickly switch between different pulse frequencies, durations, or amplitudes during pacing.

In the representative embodiment, the instrument controller **22** comprises an electrogram recorder of the type that is commercially available from, e.g., Prucka, Quinton, E for M, Bard, and Siemens. The electrogram recorder **22** functions to record, store, process, analyze, and display signals acquired by the electrodes on the basket structure **58** and as well as the roving electrode **68** during pacing.

In the representative embodiment, the instrument controller **24** comprises an appropriate controller for the imaging device **72**. The controller **24** generates a video output from the signals generated by the device **72**. The format of the video output can vary, e.g., it can comprise composite video, video-modulate RF signal, or RGB/RGBI including applicable TV standards (i.e. NTSC, PAL or SECAM).

As shown in FIG. **2**, a generator for transmitting radio frequency ablation energy can also be coupled to the roving electrode **68**, through the instrument interface **26** (as shown in solid lines in FIG. **2**), or through its own instrument interface **26'** (shown in phantom lines in FIG. **2**) coupled to the MPU **28**.

C. The Instrument Interface

In the illustrated embodiment (see FIG. **3**), the instrument interface **26** is centered around an application specific integrated circuit (ASIC) **80**. Alternatively, as previously stated, the interface **26** can comprise an assembly of separate components and not an integrated circuit.

In the illustrated embodiment, the ASIC **80** comprises a cross point switch matrix **82**. The matrix **82** includes a block of primary analog input pins **84** through which low level external signals from the recorder **22** and real image processor **24** can be received. A block of additional analog input pins **86** are provided, through which high level external signals, such as those produced by the stimulator **20** or generator **78**, can be received. The matrix **82** includes a block of analog output pins **88**.

The matrix **82** enables any of the input pins **84**/**86** to be connected to any of the output pins **88**. This operation permits, for example, various subsets of the electrodes **18** on the basket structure **58** to be connected to various subsets of input channels **116** of the electrogram recorder **22**. In addition, any of the high level input pins **86** can be coupled to any of the primary input pins **84**. This permits pacing pulses generated by the stimulator **20** to be applied through any of the electrodes **18** on the basket structure **58** or through the roving electrode **68**. Alternatively, high level pacing pulse signals can be switched backward from any of the output pins **88** to any of the input pins **84**, to permit "retrograde" pacing from the electrogram recorder **22**, if it has pacing output capabilities. The various instruments **12**, **14**, and **16** are coupled to the ASIC **80** through appropriate isolation circuitry (not shown), which isolates the ASIC **80** from potentially damaging signals, currents and voltages.

The ASIC **80** includes embedded on-chip software that comprises a switch manager **90**. In response from high level commands from the MPU **28** (which are generated by the selected application A1 to A7 or function F1 or F2 run by the operating system **44** on the MPU **28**), the switch manager **90** configures the cross point switch matrix **82** to establish desired electrical connections among the various instruments **12**, **14**, and **16** and controllers **20**, **22**, and **24**, to carry out various operating modes for the system **10**.

The number and type of operating modes controlled by the switch manager **90** in large part parallel the number and type of applications A1 to A7 and functions F1 and F2 available for execution by the operating system **44**.

For example, when the procedure applications A1 and A2 are executed, the switch manager **90** enters a procedure mode. In this mode, the manager **90** configures the multiple electrodes **18** on the basket structure **58** and the roving electrode **68** for recording or pacing based upon the command signals generated by the MPU **28**.

The procedure mode carried out by the switch manager **90** is not necessarily constrained by the data channel limitations of the associated instrument controllers. For example, if the procedure application A1 or A2 calls for signal acquisition or pacing from sixty-four (64) electrodes, and the data acquisition capabilities of the electrogram recorder **22** happens to be only twenty-four (24) channels **116**, the switch manager **90** configures the sixty-four (64) electrodes into four subsets of sixteen (16) electrodes, switching among the subsets to achieve the desired data acquisition task using the available channels **116** of the recorder **22**. The interface **26** displays a visual PACE output, e.g., through a LED **92** on an exterior panel **114**, which is activated when the stimulator **20** is, coupled by the manager **90** to one or more instrument electrodes.

When the navigation application A3 or A4 is executed, the manager **90** is commanded by the MPU **28** to enable the navigation mode. During the navigation mode controlled by the virtual navigation application A3, the manager **90** periodically communicates to the MPU **28** the electrically sensed position of the roving electrode **68** for display in the GUI **46**, using an embedded navigation routine **94**, which will be described in greater detail later. In a preferred embodiment, the position reporting frequency is at least once per heart chamber cycle (i.e., once every 150 ms or greater).

When the navigation mode is controlled by real image application A4, the manager **90** inputs signals from the imaging device **72** to the processor **24**, and outputs processed video signals to the MPU **28** for display on the GUI **46**.

The interface displays visual NAVIGATION DISABLED and NAVIGATION ENABLED outputs, e.g., through LEDs **96** and **98** on the exterior panel **114**. The NAVIGATION ENABLED LED **98** is activated when either navigation application A3 or A4 is executed and the navigation mode is enabled. Conversely, the NAVIGATION DISABLED LED **96** is activated when neither navigation application A3 or A4 are executed.

In an illustrated embodiment, the multiple electrode instrument **12** carries an electrical identification code **100**, which uniquely identifies the physical property and configuration of the electrodes on the basket structure **58**. The switch manager **90** includes an embedded ID routine **102**, which electrically senses the code **100** and inputs configuration data according to the code **100** for use in the navigation routine **94**. The code **100** can be variously implemented, e.g., in an integrated circuit, which expresses the code **100** in digital form, or as separate electrical elements, such as several resistors having different resistance values which express the digits of the code **100**.

In the illustrated embodiment, application A5 constitutes a prescribed testing utility. When the testing application A5 is executed on the MPU **28**, the switch manager **90** responds to high level commands generated by the application A4 to stop recording, pacing, and navigation switching tasks, and configure the cross point switch matrix **82** to perform various prescribed system tests, e.g., open or short-circuit detection and confirmation of system connections. More details of these and other utility applications A6 and A7 will be described later. The interface displays a visual TEST output, e.g., through a LED **104** on the exterior panel **114**, which is activated when the testing application A5 is executed.

In a preferred embodiment, the embedded on-chip switch manager **90** also runs a self-test routine **106** immediately after power-on or hardware reset. In the self-test mode, the manager **90** verifies the overall functionality of the interface **26**. The embedded on-chip switch manager **90** also continuously self-checks the interface's functionality, e.g., through a conventional watchdog routine **108**, which interrupts improper software execution. When a failure is detected (or when the self-test mode fails), the manager **90** switches to a safe mode, where command execution is inhibited and the navigation mode is disabled. The interface **26** displays a visual WARNING output, e.g., through a LED **110** on the exterior panel **114**, which is activated when the safe mode is entered. The interface remains in the safe mode until the user presses a reset button **112** on the exterior of the interface **26** to continue.

D. The Operator Interface and GUI

In the illustrated embodiment, the graphics display device **38** of the operator interface **36** supports SVGA or comparable display of graphic information by the GUI **46**. The MPU **28** preferable has a SPECfp92 benchmark of at least 25 to support rapid update of graphical information on the GUI **46**.

1. Start-Up

Upon boot-up of the MPU **28**, the operating system **44** implements the GUI **46**. The GUI **46** displays an appropriate start-up logo and title image, followed by the START-UP screen **118**, as shown in FIG. **4**.

The START-UP screen **118** includes a column of icon push button controls **120** to **134**, which are labeled for each of the main operating modes or functions available to the MPU **28** for execution.

The illustrated embodiment provides these executable modes: RECORDING PROTOCOLS (executing Application A1); PACING PROTOCOLS (executing Application A2); VIRTUAL IMAGE NAVIGATION (executing Application A3); REAL IMAGE NAVIGATION (executing Application A4); TEST (executing Application A5); PRINT (executing Application A6); and SERVICE (executing Application A7). Selected a button control **120** to **134** using the pointing device **42** or keyboard **40** (or touching the screen itself, if a touch screen feature is provided), causes the operating system **44** to down load and implement the associated application on the MPU **28**.

In the illustrated embodiment, the additional icon push button control **134** labeled EVENT LOG is present on the start up scree **118**. This control **134**, when selected, toggles on and off the display of an event log, which the Event Log Function F1 of the operating system **44** continuously executes in the background. The Event Log Function F1 records specified major events that occur during the course of a given procedure. More details about the Event Log Function F1 and the EVENT LOG toggle button **134** will be provided later.

As will be demonstrated later, each of these push button controls **120** to **134** are displayed by the GUI **46** throughout a given operating session, regardless of what application is being executed. The push buttons **120** and **132** for the executable modes are displayed in one color (e.g., grey) when not selected and a different color (e.g., green) when selected. The label of the toggle push button **134** changes when selected.

In the illustrated embodiment, the operating system **44** itself is not available for general use by the operator, outside of the confines of the GUI **46**. Access to the operating system **44** is restricted only to authorized service personnel, through executing the password protected SERVICE application A7, which will be described later.

Further details of the GUI **46** will be now described by selecting and executing the applications A1 to A7, as well as describing the execution of the functions F1 and F2.

2. Recording Protocols Application (A1)

The selection of the RECORDING PROTOCOLS push button **120** executes the recording protocols application (A1). The recording protocols application A1 operates to define or configure electrode subgroups among the available electrodes **18** of the basket **58** and roving electrode **68**, to feed myocardial signal data from the subgroups to the input channels **116** of the recorder **22**.

The recording protocols application A1, when executed by the MPU **28**, displays a first sub-window **136**, as shown in FIG. **5**. As can be seen in FIG. **5**, all main mode and function push buttons **120** to **134** remain displayed on the right side of the window **136**. The selected push button **120** changes color when selected, while the other non-selected push buttons **122** to **134** remain displayed in their original state.

The first sub-window **136** allow the operator to define a Recording Configuration and a Recording Sequence. By selected the CONFIGURATION control tab **138** or the SEQUENCE control tab **140**, the operator is able to switch between the recording configuration window **136** (shown in FIG. **5**) and a recording sequence window **142** (shown in FIG. **6**).

a. Recording Configuration

The recording configuration window **136** displays an INPUT CHANNEL column field **144**, a CATHETER TYPE column field **146**, and an ELECTRODE column field **148**. Information in these fields **144**, **146**, and **148** together define a currently valid Catheter Configuration, which is assigned by default or by the operator an identifier in a RECORD CONFIGURATION field **150**. The recording configuration window **136** also displays an OUTPUT CHANNEL field **170**, which assigns an output channel number to each electrode, which also becomes a component of the valid Catheter Configuration **150**.

A catheter configuration can be saved as a file on the hard drive, for processing, editing, and retrieval. Various file management push button controls (CREATE **152**, OPEN **154**, SAVE **156**, DELETE **158**, and APPLY **160**) are provided for this purpose.

The INPUT CHANNEL field **144** identifies the input channels **116** of the recorder **22**. The OUTPUT CHANNEL field **170** identifies the output channel assigned to each electrode. By default, the rows are indexed by INPUT CHANNEL in numeric or alpha-numeric order. Alternatively, the operator can index in channel output order, by selecting the SORT BY OUTPUT control button **162**. When selected, the SORT BY OUTPUT control button label toggles to SORT BY INPUT. The operator can always select indexing the display either between recorder input channel or electrode output channel.

The operator can scroll using the control buttons **164**, up and down the INPUT CHANNEL field **144** in conventional fashion. In the illustrated embodiment, the scrolling occurs in steps of sixteen, and information is updated across all fields **144**, **146**, and **148** while scrolling.

For each INPUT CHANNEL, the recording protocols application A1 accepts a STATUS field input **166**, which indicates an non-operational state of the channel (e.g., shorted or open). No input in the STATUS field **166** (i.e., a blank field) indicates a good operational channel. The STATUS field **166** receives input from the test application A5, or from self-tests conducted by the switch manager **90**, as already described.

The INPUT CHANNEL field **144** can be edited by the operator, to associate available electrodes **18** or **68** with available recorder input channels **116**, as desired. As earlier explained, the operator can configure the INPUT CHANNELS into electrode subgroups, so a recorder **22** having a lesser number of input channels than the number of electrodes can nevertheless be used to record and process signals obtained by the multiple electrode basket **58**. For example, to configure sixty-four 64) electrode channels for input using a thirty-two (**32**) channel recorder, electrodes A1 to D8 define the first electrode subgroup, and E1 to H8 define the next electrode group.

The OUTPUT CHANNEL field **170** can likewise be edited using a drop down menu control **168** or by input from the keyboard **40**. The OUTPUT CHANNEL field **170** accepts a numeric value from between 1 to 72.

The CATHETER TYPE field **146** contains an key word identifier, which indicates the type of instrument carrying the electrodes **18** or **68**, e.g., whether it is a multiple electrode basket structure **58** (which is designated "Constellation" in FIG. **5**, which in shorthand identifies a CONSTELLATION® Catheter sold by EP Technologies, Inc.), or a roving electrode **68** (for example, in shorthand, "Roving"), or some other type of identifiable electrode configuration or shape typically used by electrophysiologists (for example, in shorthand, "HIS, CS, HRA, RVA," etc.).

The CATHETER TYPE column field **146** is editable, either by predefined default drop down menu control **168** or by input from the keyboard **40**. Thereby, the operator can, in a single record configuration, associate with the recorder input channels, several different types of electrodecarrying instruments, e.g., a multiple electrode basket **58** and a roving electrode **68**, and others.

The ELECTRODE field **148** identifies each electrode **18** on the instrument by the assigned numeric, alphabetic, or alpha-numeric code. As already explained, for the basket **58**, the electrodes **18** are identified A1, B4, C6, etc., with the splines alphabetically identified (A, B, C, D, etc.), and the electrodes on each spline numerically identified from the distal to the proximal end of the spline (1, 2, 3, etc.). Instruments with a single electrode or linear or curvilinear arrays of electrodes, like the roving electrode **58**, can numerically identify electrodes in order from distal to proximal end of the instrument. The ELECTRODE column field **148** is editable, either by predefined default drop down menu controls **168** or by input from the keyboard **40**.

Selecting the file management control buttons (CREATE **152**, OPEN **154**, SAVE **156**, DELETE **158**), the operator can, respectively, establish a new record configuration, retrieve an existing record configuration as a file from the hard drive **32**, save a new or edited record as a file to the hard drive **32**, or delete a record file from the hard drive **32**. By selecting the APPLY control button **160**, the operator commands the instrument interface **26** to be configured according to the current recording configuration.

b. Record Sequence

The record sequence window **142** (see FIG. **6**) is displayed by selecting the Sequence tab **140**. The window **142** lists the recording sequences and the order in which they are applied to the recorder **22** via the instrument interface **26**. The window **142** displays a CONFIGURATION column field **172**, a SEQUENCE TYPE column field **174**, a DURATION column field **176**, a #PULSES column field **178**, and a #CYCLES column field **180**. Each row of information in these fields **174** to **180** together define a recording protocol. The numeric order in which the protocols are listed comprises a recording sequence. In the illustrated embodiment, the window **142** allows for a maximum of fourteen rows, that is, fourteen different recording protocols for each recording sequence.

Each recording protocol (row) in a given recording sequence is assigned a file name **182**, either by default or by the operator for storage in the hard drive, with a ".rec" file identifier. The hard drive **32** can carry pre-determined recording protocols as .rec files, so that the operator need not be concerned about inputting the specifics of the recording sequence. The file name **182** appears in the CONFIGURATION field **172**. The recording sequence, which lists the order of the protocols, is also assigned a file name **184** for storage in the hard drive **32**, either by default or by the operator. This file name **184** appears in the editable Record Sequence field.

Various file management push button controls (CREATE **186**, OPEN **188**, SAVE **190**, DELETE **192**, ADD ROW **194**, REMOVE **196**, and APPLY **198**) are provided for establishing, retrieving, saving, removing, or otherwise editing recording files retaining the protocols and recording sequences configurations.

The SEQUENCE TYPE field **174** constitutes a control button, which toggles between Automatic mode and Manual mode. When set to Automatic mode, the recording application A**1** applies the protocol row to the interface box without requiring operator intervention, following the timing specified either in the DURATION field **176** or #PULSES field **178**, as will be described later. When set to Manual mode, the recording application A**1** requires operator intervention before applying the protocol. In the illustrated embodiment, the operator intervenes by selecting the NEXT control button **200** in the sequence window **142**.

The DURATION field **176**, the #PULSES field **178**, and the #CYCLES field **180** are each editable by input from the keyboard **40**. The number inserted by the operator in the DURATION field **176** specifies the number of seconds for which the specified protocol is to be applied to the instrument interface **26**. The number inserted by the operator in the #PULSES field **178** specifies the number of pacing pulses for which the specified protocol is to be applied to the instrument interface **26**. The longer of the time period specified in the DURATION field **176** and #PULSES field **178** controls the timing of the protocol applied to the instrument interface **26**. The number inserted by the operator in the #CYCLES field **180** specifies the number of cycles for which either the duration field value or pacing pulse field value controls the application of the protocol to the instrument interface **26**.

By selecting the file management control buttons (CREATE **186**, OPEN **188**, SAVE **190**, DELETE **192**), the operator can, respectively, establish a new record configuration, retrieve an existing record as a file from the hard drive **32**, save a new or edited record as a file to the hard drive **32**, or delete a record file from the hard drive **32**.

By selecting the ADD ROW control button **194**, the operator adds a new row of editable fields, in which the operator can add a new recording protocol for the recording sequence, which is assigned the next sequential row number. Conversely, by selecting the REMOVE control bottom **196**, the operator can remove any highlighted protocol row.

By selecting the APPLY control button **198**, the recording application A**1** commands the instrument interface **26** to be configured to carry out the recording sequence specified in the record sequence window **142**. The recording application A**1** starts applying the sequencing row by row to the instrument interface **26** in row order. The recording application A**1** displays a highlight **202** around the sequence row that is being currently applied to the instrument interface **26**.

By selecting the PAUSE control button **204**, the recording application A**1** interrupts the sequencing. The control button label toggles to RESUME, which permits, when selected, the resumption of the sequencing, toggling the label back to PAUSE.

By selecting the RESET control button **206**, the recording application A**1** begins sequencing at the first listed row, regardless of the current status of the sequence. The RESET control button **206** is active for selection only when the sequencing is paused or otherwise not being applied. Furthermore, changes to any editable field in the window **142** are accepted only when the sequencing is paused or not being applied.

3. Pacing Protocols Application (A**2**)

The selection of the PACING PROTOCOLS push button **122** executes the recording protocols application A**2**. The pacing protocols application A**2** operates to define or configure the connectivity among the one or more pacing stimulators **20** and the electrodes connected via the instrument interface **26**.

The pacing protocols application A**2**, when executed by the MPU **28**, displays a first sub-window **208**, as shown in FIG. **7**. As can be seen in FIG. **7**, the main mode or function push buttons **120** to **134** still remain in view on the right side of the window **208** in their original first color, except the selected push button control **122**, which changes color when selected.

The first sub-window **208** allow the operator to define a Pacing Configuration and a Pacing Sequence. By selected the CONFIGURATION control tab **210** or the SEQUENCE control tab **212**, the operator is able to switch between the pacing configuration window **208** (shown in FIG. **7**) and a pacing sequence window **214** (shown in FIG. **8**). This GUI architecture parallels that of the recording application (A**1**), just described.

a. Pacing Configuration

The configuration window **208** displays an INPUT CHANNEL column field **216**, a TERMINAL TYPE column field **218**, an ELECTRODE column field **220**, and a TERMINAL column field **222**.

The information contained in the INPUT CHANNEL field **216**, the TERMINAL TYPE field **218**, and the ELECTRODE field **220** corresponds to the information inputted by the operator on the current recording configuration window **136** (FIG. **5**) in the INPUT CHANNEL field **144**, CATHETER TYPE field **146**, and ELECTRODE field **148**, respectively. The recording configuration name in current recording configuration window **136** (FIG. **5**) (i.e., "constell") also appears in the PACE CONFIGURATION field **224** of the pacing configuration window **208**. The pacing application A**2** does not allow the operator to edit these fields **216**, **218**, and **220** in the pacing configuration window **208**, thereby maintaining conformity between the current recording configuration and the current pacing configuration. For each INPUT CHANNEL **216**, the pacing protocols application also displays a STATUS field input **226**, which corresponds with the information in the STATUS field **166** in the current recording configuration window **136** (FIG. **5**). The operator can scroll using the control buttons **228**, up and down the rows in known fashion, which, in the illustrated embodiment, is in steps of sixteen. Information across all fields is updated during scrolling.

The only editable field in the pacing configuration window **208** is the TERMINAL column field **222**. The editable TERMINAL field **222** allows for selection of known electrode terminals by a drop down menu control **230**. The drop down menu **230** contains the selections: "None", "1", "1+", "2–", and "2+". The pacing application A2 replaces a previously entered value of the TERMINAL field **222** in a different row with "None" whenever the operator selects the same terminal value in another row from the drop down menu **230**.

Selecting the file management control buttons SAVE **236** or DELETE **238**, the operator can save a new or edited record as a file to the hard drive **32**, or delete a record file from the hard drive **32**. The CREATE **232** and OPEN **234** control buttons are not active on the pacing configuration sheet, as a pacing configuration can be established or retrieved only in conjunction with the establishment or retrieval of a recording configuration, through the recording applications **A1**.

By selecting the APPLY control button **240**, the operator commands the instrument interface **26** to be configured according to the current pacing configuration. When the APPLY button **240** has been selected, a DISCONNECT STIMULATOR control button **242** appears in the window **208**, preferably in red or another distinguishing color. The DISCONNECT STIMULATOR button **242** allows the operator to immediately interrupt transmission of the pacing inputs to the hardware interface **26**. The DISCONNECT STIMULATOR control button **242**, once implemented, continues to be displayed throughout the remainder of the operating session, regardless of what application is implemented, unless selected to interrupt pacing.

b. Pacing Sequence

Selection of the Sequence tab **212** in the configuration window **208** opens the pacing sequence window **214** shown in FIG. **8**. The pacing sequence window **214** lists the pacing protocols and the order in which they are applied to the stimulator **20** via the instrument interface **26**.

The window **214** displays a CONFIGURATION column field **244**, a SEQUENCE TYPE field column **246**, a DURATION column field **248**, a #PULSES column field **250**, and a #CYCLES column field **252**. Each row of information in these fields **244** to **252** together define a pacing protocol. The numeric order in which the protocols are listed comprises a pacing sequence. In the illustrated embodiment, the window **214** allows for a maximum of fourteen rows, that is, fourteen different pacing protocols for each pacing sequence.

Each pacing protocol (row) in a given pacing sequence is assigned a file name **254**, either by default or by the operator for storage in the hard drive **32**, with a ".pac" file identifier. The hard drive **32** can carry pre-determined pacing protocols as .pac files, so that the operator need not be concern about inputting the specifics of the pacing sequence. The file name **254** appears in the CONFIGURATION field **244**. The pacing sequence, listing the order of the protocols, is also assigned a file name **256** for storage in the hard drive **32**, which is the same name assigned to the current recording sequence (i.e. "test"), which appears in the Pacing Sequence field **258**.

The SEQUENCE TYPE field **246** constitutes a control button, which toggles between Automatic mode and Manual mode. When set to Automatic mode, the pacing application A2 applies the protocol row to the instrument interface **26** without requiring operator intervention, following the timing specified either in the DURATION field **248** or #PULSES field **250**, as will be described later. When set to Manual mode, the pacing application requires operator intervention before applying the protocol. In the illustrated embodiment, the operator intervenes by selecting the NEXT control button **260** in the sequence window **214**.

The DURATION field **248**, the #PULSES field **250**, and the #CYCLES field **252** are each editable by keyboard entry. The number inserted by the operator in the DURATION field **248** specifies the number of seconds for which the specified protocol is to be applied to the interface **26**. The number inserted by the operator in the #PULSES field **250** specifies the number of pacing pulses for which the specified protocol is to be applied to the interface **26**. The longer of the time period specified in the DURATION field **248** and #PULSES field **250** controls the timing of the protocol applied to the interface **26**. The number inserted by the operator in the #CYCLES field **252** specifies the number of cycles for which either the duration field value or pacing pulse field value controls the application of the protocol to the interface **26**.

Selecting the file management control buttons (CREATE **262**, OPEN **264**, SAVE **266**, DELETE **268**), the operator can, respectively, establish a new record configuration, retrieve an existing record as a file from the hard drive **32**, save a new or edited record as a file to the hard drive **32**, or delete a record file from the hard drive **32**. By selecting the ADD ROW control button **270**, the operator adds a new row of editable fields, in which the operator can add a new recording protocol of the recording sequence, which is assigned the next sequential row number. By selecting the REMOVE control button **272**, the operator can remove any highlighted protocol row.

By selecting the APPLY control button **274**, the pacing application A2 commands the instrument interface **26** to be configured to carry out the pacing sequence specified in the pacing sequence window **214**. The pacing application A2 starts applying the sequencing row by row to the instrument interface **26** in the order specified. The pacing application A2 applies a highlight **276** about the sequence row in the window **214** that is being currently applied to the instrument interface **26**.

When the APPLY button **274** has been selected, the DISCONNECT STIMULATOR control button **242** appears, preferably in red or another distinguishing color, to allow the operator to immediately interrupt transmission of the pacing inputs to the instrument interface. As before described, the DISCONNECT STIMULATOR control button **242**, once implemented, continues to be displayed throughout the remainder of the operating session, regardless of what application is implemented, unless selected.

By selecting the PAUSE control button **278**, the pacing application A2 temporarily interrupts the pacing sequence. The control button label toggles to RESUME, which permits, when selected, the resumption of the sequencing, toggling the label back to PAUSE.

By selecting the RESET control button **280**, the recording application begins sequencing at the first listed row, regardless of the current pacing status. The RESET control button **280** is active for selection only when the sequencing is paused or not otherwise being applied. Furthermore, changes to any editable field on the sheet is accepted only when the sequencing is paused or not being applied.

4. Virtual Image Navigation Application (A3)

The selection of the VIRTUAL IMAGE NAVIGATION push button control **124** runs the virtual navigation application A3. The navigation application A3, when executed by the MPU **28**, displays a virtual navigation window **282**, as shown in FIG. **9**. As can be seen in FIG. **9**, the main application control push buttons **120** to **134** still remain in view on the right side of the navigation window **282** in their original first color, except the selected VIRTUAL IMAGE NAVIGATION push button control **124**, which changes color when selected.

a. Basket Display

The virtual image navigation application A3 generates in the window **282** an idealized graphical image **284**, which models the geometry of the particular multiple electrode instrument **12** deployed in the body region. In the illustrated embodiment, the instrument **12** is the three-dimensional basket **58**, shown in FIG. **2**, and the image **284** reflects this geometry modeled as a wire-frame image. By reference to this model image **284**, the physician is able to visualize the location of each electrode and spline on the basket **58**, as well as view the location of the roving electrode **68** relative to the basket image **284**.

In the illustrated and preferred embodiment, the navigation application A3 provides split screen images (designated **284**L and **284**R) in a left panel **286** and a right panel **288**.

To facilitate the creation of the images **284**L and **284**R, the electrical identification code **100** of the basket **58**, previously described, also identifies the geometry and layout of electrodes on the basket **58**. The navigation application A3 calls upon a library of idealized graphical images in hard drive storage **54**, which reflect the different geometries identified by the code **100**. Based upon the code **100**, the navigation application A3 generates an idealized graphical image that corresponds to the geometry of the particular one in use. Alternatively, the toolbar **296** can include a Basket Size push button **342**, which, when selected, opens a dialog box from which the operator can select one basket size from a listing of basket sizes.

In the illustrated embodiment (in which the array is a three dimensional basket **58**), the model wire-frame image displays splines A to H in a selected first color, except for spline A, which is preferably displayed in a different color for reference and orientation purpose. By selecting the toggle Show Splines control button **340**, the left and right images **284**L and **284**R display alphabetical spline labels A through H. The control button **340** toggles between Show Splines and Hide Splines, which removes the alphabetic labels.

In the left view, the X-axis of the image **284**L is aligned by default along the major head-to-foot axis of the patient, the Y-axis is aligned along the shoulder-to-shoulder axis of the patient, and the Z-axis is aligned along the front to-back axis of the patient. The color of the splines A to H is preferably displayed in different hues or shades to indicate their three-dimensional orientation along the Z-axis of this coordinate system, e.g., a bright shade when the spline appears in the foreground (when the Z value>0) and a dark shade when the spline appears in the background (when the Z value<0). The idealized electrodes N can be represented by small rectangles or nodes.

In the illustrated embodiment (see FIG. **10**), whenever the operator places the pointing device **42** over a given electrode N, a pop-up window **292** displays the location of a selected electrode N by spline electrode designation (A1, B2, etc., as explained above). When a pace sequence has been applied, the pop-up window **292** displays a menu **294**, which highlights the pacing terminal type of the electrode (1+, 1−, 2+, 2−). If the pointing device **42** selects the roving electrode **68**, the pop-up window **292** will identify it as "Roving."

As FIG. **9** shows, the left and right panels **286** and **288** make it possible to simultaneously display the images **284**L and **284**R from different idealized orientations. The navigation application A3 generates an Operational Screen Toolbar **296**, which provides the physician with a variety of options to customize the idealized image **284**L and **294**R in each panel **286** and **288**. Using the Toolbar **296**, or by entering associated short-cut command entries using the keyboard **40**, the physician is able to set up the desired images **284**L and **284**R in the left and right panels **286** and **288**.

In the illustrated embodiment (see FIG. **9**), the Toolbar **296** includes an array of Left View Control Buttons **298** for the image **284**L displayed in the left panel **286**. The left panel **286** shows the image **284**L from preset right or left anterior angles or preset right or left posterior oblique angles. The Left View Control Buttons **298** allow the physician to choose among the preset orientations for the left image **284**L, such as Left 45° or 30° (labeled respectively LAO45 and LAO30 in FIG. **9**), Right 45° or 30° (labeled respectively RA**045** and RAO**30** in FIG. **9**), or Anterior/Posterior (labeled AP in FIG. **9**). An Edit Control field **316** displays the currently selected preset orientation.

The Toolbar **296** also includes three sets of Orientation Control Buttons **304**(X), **304**(Y), and **304**(Z) to customize the viewing angle for the left image **284**L. The buttons **304**(X,Y,Z), when selected, cause the left image **284**L to rotate about an idealized coordinate system located at center of the image **284**L. Selection of the button **304**(X) rotates the image **284**L in either a left-to-right or right-to-left direction. Selection of the button **304**(Y) rotates the image **284**L in either a top-to-bottom or bottom-to-top direction. Selection of the button **304**(Z) rotates the image in either a clockwise or counterclockwise direction. Alternatively, or in combination with the Orientation Control buttons **304**(X,Y,Z) the navigation application A3 can provide for rotation of the left image **284**L by conventional "dragging" of the pointing device **42**.

The Orientation Angles for the present left image **284**L are displayed in the fields **306** (X), **306** (Y), and **306**(Z), respectively, on the Toolbar **296**. The Toolbar **296** includes a RESET **312** button, which, when selected, inputs predefined default values as Orientation Angles in the fields **306**(X), **306**(Y), and **306**(Z), and the left image **284**L is redrawn accordingly.

The Edit Control field **316** includes a control button **318**, which activates a drop down menu. The drop down menu lists the prescribed preset orientations (LAO45, LAO30, RAO45, RAO30, and AP) for selection. The drop down menu also permits the physician to include on the listing a title identifying a custom orientation set up using the Orientation Control buttons **304**(X,Y,Z). The physician is thereby able to set up and use custom orientations, along with the preset orientations.

The image **284**R displayed in the right panel **288** is displayed from a selected orthogonal side angle relative to the left image **284**L. The orientation of the right image **284**R is adjusted to reflect the adjustments in the orientation of the left image **284**L. An array of Right View Control Buttons **300** allows the physician to select among preset orthogonal views for the right image **284**R, e.g., as labeled in FIG. **9**, Superior, Inferior, Left **90**, and Right **90**. The preset Superior view is offset relative to the left image **284**L 90 degrees about the Y-axis and **180** about the X-axis. The preset Inferior view is offset relative to the left image **284**L minus 90 degrees about the Y-axis. The preset Left **90** view is offset relative to the left image **284**L 90 degrees about the X-axis. The preset Right **90** view is offset relative to the left image **284**L minus 90 degrees about the X-axis. A field **332** displays the name (e.g., Superior) of the selected preset view of the right image **284**R.

In the illustrated embodiment, the navigation application **A3** displays orientation arrows **302** in the left panel **286** to assist the operator in establishing the relationship between the left and right panel images **284**L and **284**R. The orientation arrows **302** point at the left image **284**L along the horizontal or vertical axis of the line of sight along which the right image **284**R is viewed for display in the right panel **288**. As FIG. **9** also shows, the right panel **288** is also labeled Anterior (front) and Posterior (rear) to further help the physician orient the right image **284**R. Other graphical clues, such as a bitmap human figure or small coordinate axes may be displayed to aid orientation.

In addition, the Toolbar **296** includes Fluor Angle Control buttons **320** and associated Fluoro Angle field **322**. When selected, the buttons **320** rotate both the current left and right images **284**L and **284**R about the X-axis. The Fluoro Angle field **322** changes accordingly from zero to plus or minus 90 degrees. The buttons **320** allow the physician to match the orientation of the virtual images **284**L and **284**R with the orientation of a real image of the basket **58** provided by the imaging device **72**. More details of this aspect of the system will be described later.

The Zoom Left push button **344** and the Zoom Right push button **346**, when selected, allow the operator to call up a full-screen image of, respectively, the left image **284**L or the right image **284**R. All functions of the toolbar **296** remain function for the selected zoom image.

b. Binary Map Displays

In the illustrated embodiment, the Toolbar **296** (see FIG. **9**) includes control buttons, which integrate for viewing in the display panels **286** and **288** functions performed by the record protocols application **A1** and the pacing protocols application **A2**, previously described.

The SHOW PACE push button **290**, when selected, opens in the right panel **286** a modified version of the Pacing Configuration window **208** (shown in full form in FIG. **7**). The modified version displayed upon selection of the SHOW PACE button **290** includes the Pace Configuration field **224**, the scroll bar **228**, the Input Channel Field **216**, the Terminal field **222**, along with the SAVE **236**, DELETE **238**, and APPLY **240** control buttons.

The NEXT REC push button **308** on the Toolbar **296** has the same function as the Next control button **200** on the Record Sequence window **142** (see FIG. **6**), by advancing the record sequence to the next row when the current row is designated Manual in the Type field **174** of the Record Sequence window **142**. Similarly, the NEXT PACE push button **338** on the Toolbar **296** has the same function as the Next control button **260** on the Pace Sequence window **214** (see FIG. **8**), by advancing the pace sequence to the next row when the current row is designated Manual in the Type field **246** of the Pace Sequence window **214**.

The toolbar **296** also includes a Binary Map push button **348**. When selected (see FIG. **11**), the Binary Map push button **348** opens a push button selection menu **368** on the toolbar **296**, listing CREATE MAP **350**, SHOW MAPS **352**, CLEAR MAPS **354**, REMOVE MAP PTS **356**, CLOSE **358**, and MAP LEGENDS **360**.

Selection of the CREATE MAP button **350**, in turn, opens a sub menu **362** on the toolbar **296**, which lists the default selections for the binary maps, along with a CLOSE button **370**. In the illustrated embodiment, the sub menu **362** lists as map selections early activation, fractionation, good pace map, concealed entrainment, and user defined. When one of the listed choices is selected, the application **A3** executes the desired mapping function based upon input from the record and pace applications **A1** and **A2**.

To facilitate interpretation of the selected binary map, the application **A3** annotates the images **284**L and **284**R with graphical symbols, called Binary Map Designators **364**. The Designators identify by shaped and colored symbols the recording electrodes, the pacing electrodes, the roving electrode **68**, and regions of electrical activity that the selected map function seeks out. Selecting the MAP LEGENDS button **360** (see FIG. **12**) opens a sub menu **366**, which lists the Binary Map Designators **364** by type, shape, and color. Using the pointing device **42**, the operator is able to select among the individual electrodes on the displayed images **284**L and **284**R, to designate (e.g., by clicking) which electrode is to serve as a pacing electrode or as a recording electrode. The operator is thereby able to control the pacing and recording activities using the images **284**L and **284**R on the display panels **286** and **288**.

The type of electrical activity highlighted by the Designators depends upon the type of binary map selected. For example:

The early activation map identifies and marks with the appropriate Binary Map Designator the electrodes where early depolarization of the heart tissue has occurred (early depolarization is often an indicator of abnormal heart tissue adjacent the electrode).

The fractionation map identifies and marks with the appropriate Binary Map Designator the electrodes where the electrograms sensed by such electrodes appear fractionated or broken in appearance (again, the existence of fractionated electrograms a particular electrode site is often an indicator of abnormal cardiac tissue at that site).

The good pace map identifies and marks with the appropriate Binary Map Designator the electrodes with a high pace mapping matching index. This index reflects how many of the morphologies of 12-lead surface electrocardiograms (ECG) acquired during non-induced arrhythmia match the morphologies of the same signals acquired during paced induced arrhythmia from the particular electrode. If by pacing from a particular electrode, a high number of the 12-lead ECG morphologies are similar during non-induced and pace-induced arrhythmia then it is likely that the particular electrode **18** resides close to an arrhythmogenic focus.

The concealed entrainment map identifies and marks with the appropriate Binary Map Designator the electrodes where arrhythmia entrainment was achieved (abnormal cardiac tissue often is located electrodes exhibiting concealed entrainment).

The user defined map function enables the operator to place a operator-specified Binary Map Designator on the displayed image **284**L or **284**R. The operator may position the graphical symbol by pointing and clicking the pointing device **42** on the selected electrode or spline region displayed on an image **284**L or **284**R. The operator can thus locate areas of cardiac tissue exhibiting certain preselected characteristics.

By selecting the SHOW MAPS button **352**, the application **A3** opens a dialog box listing all existing binary maps that have been created. Using the pointing device **42**, the operator can quickly select and switch among any existing binary map. The ability to chose among different mapping functions are of importance in identifying potential ablation sites. Frequently, abnormal cardiac tissue, which can be effectively treated through ablation, often exhibits more than one abnormal characteristic. Such sites frequently appear on two or more of the early activation, fractionation and concealed entrainment maps. If the same electrode or groups of electrodes appear on two or more of the early activation, fractionation, good pace map and concealed entrainment maps, a likely site for ablation is particularly well indicated.

By selecting a Binary Map Designator **364** on one of the images **284**L or **284**R, and then selecting the REMOVE MAP PTS button **356** on the selection menu **368** (see FIG. **11**), the operator deletes the selected Designator **364**. By selecting the CLOSE button **370** on the selection sub menu **362**, the application A3 dismisses the selection menu **362**, deselects all Designators **364**, and returns control to the main menu **368**.

Selecting the CLEAR MAPS button **354** deletes and clear all existing binary maps. Selecting the CLOSE button **358** dismisses the section menu **368** and returns control to the navigation window **282** (shown in FIG. **9**).

c. Anatomic Features Displays

The toolbar **296** also includes a Features push button **372**. When selected (see FIG. **13**), the Features push button **372** opens a push button selection menu **374**, with buttons for selecting Atrial Anatomic Features **376** or Ventricular Anatomic Features **378**. Selection of the button **376** or **378** opens a dialog box **380** for the selected region. The selection box **380** includes an anatomic features field **382** (listing e.g., the aortic valve, the inferior vena cava, the superior vena cava, etc.), along with control buttons labeled CLEAR ALL **384**, REMOVE **386**, and CLOSE **388**. The application A3 maintains an editable text file, from which the features **382** in the field **382** are inputted.

Using the pointing device **42**, the operator selects a feature from the field **382**, drags the selected feature to an image **284**L or **284**R, and drops the selected feature at the appropriate location on the image **284**L or **284**R. Having the relative locations of such anatomical structures displayed relative to the images **284**L and **284**R helps the physician in guiding the roving electrode **68**, and in mapping and treating the target myocardial tissue. The anatomic markers can be deleted as a group by clicking on the CLEAR ALL button **384**, or can be selectively deleted by clicking the REMOVE button **386**. Selection of the CLOSE button **388** dismisses the features selection boxes **374** and **380** and returns control to the navigation window **282** (shown in FIG. **9**).

5. Image File Management

The navigation application A3 makes possible the establishment and processing of images files by providing Management Control Buttons, labeled OPEN **310** and SAVE **314**, on the Toolbar **296** (see FIG. **9**).

By selecting the SAVE button **314**, the left image **284**L, as currently configured in the left panel **286**, is saved as an image file on the hard drive **32**. Preferably, the image file is also saved as a record in the patient data base **52**, the details of which will be described later.

When the SAVE button **314** is selected, the navigation application A3 reads the current values in the Orientation Angle fields **306**(X), **306**(Y), and **306**(Z) (which can comprise a custom orientation) and computes the data necessary to recreate the saved orientation and the other prescribed preset orientations (LAO45, LAO30, RAO45, RAO30, and AP) for the left image **284**L. Before saving, the navigation application A3 displays a dialog box asking the physician to designate which one of the preset or custom views constitutes the primary selected view.

The OPEN control button **310** allows the physician to retrieve an existing image record as a file from the hard drive **32** for further viewing and editing.

The navigation application A3 allows the physician to uniquely associate the image **284**L/R with a file record, so that the physician can quickly recall, process, edit, or switch among any previously saved image.

a. Navigation Data

The navigation application A3 also displays in the left and right panels **286** and **288** an idealized image **324** of the roving electrode **68**, showing its location relative to the idealized images **284**L and **284**R. For example, the roving electrode image **324** can appear as a square, with consideration for a Z-axis shadowing effect, as previously described for the splines. By selection of the toggle ROVING SITE button control **414**, the display of the roving electrode image **324** can show a current real-time position for the image **324** (as FIG. **9** depicts), or in a track view showing the path of movement for the image **324** over a period of time.

There are various ways to generate positionindicating information to track movement of the roving instrument relative to the basket **58**.

b. Proximity Sensing (Voltage Threshold Analysis)

In one embodiment (see FIG. **14**), an electrical field F is established inside the body region S between an electrode **18** carried by the basket **58** an indifferent electrode **326**, coupled to an electrical reference **328**. The electrode **68** carried by the roving instrument **14** senses voltage amplitudes in the field F. The magnitude of a given sensed voltage amplitude V_{SENSE} will vary according to location of the roving electrode **68** in the electric field F, and, in particular, to the distance between the transmitting basket electrode **18** and the roving electrode **68**.

The sensed voltage amplitude V_{SENSE} is compared to a threshold value V_{THRESH}. V_{THRESH} is selected based upon empirical data to reflect a voltage amplitude that occurs, given the electrical conditions established, when a selected close-to-far transitional distance (e.g., 5 mm) exists between transmitting and sensing electrodes. If the sensed voltage amplitude V_{SENSE} is equal to or greater than the threshold value V_{THRESH}, the roving electrode **68** is deemed to be in a “close condition” to the basket electrode **18** (e.g., closer than 5 mm). Otherwise, the roving electrode **68** is deemed to be in a “far condition” to the basket electrode **18**.

Still referring to FIG. **14**, the navigation application A3 can implement this methodology by initialized the electrode nodes N on the GUI **46** at a designated color or shade. The initialized color or shade for a given node N constitutes a default visual signal to the physician, that the roving electrode **68** is at the “far condition” relative to the associated basket electrode **18**.

In the navigation mode, the switch manager **90** of the ASIC **80** periodically runs an algorithm from the embedded program **94**, which assesses V_{SENSE} for the roving electrode **68** relative to each electrode **18** on the basket **58**. The manager **90** communicates the V_{SENSE} values associated with each basket electrode **18** to the navigation application A3 executed by the MPU **28**. The navigation application A3 compares each V_{SENSE} to a selected V_{THRESH}. The navigation application A3 switches “ON” a given node N on the GUI **46**, e.g., by changing the designated color, shape, or shade or by flashing the node N, whenever the comparison indicates that the roving electrode **68** is in a “Close Condition” relative to the electrode **18** to which the node N corresponds.

In a preferred embodiment, as FIG. **15** shows, the physician is able to select open a pop-up Sensitivity Adjustment Window **330**. The Window **330** allows the physician to alter the spacial sensitivity for the proximity-indicating output, i.e, by changing the threshold value V_{THRESH} used by the navigation application A3.

It is possible for more than one node to be switched "ON" at the same time, depending upon the orientation of the roving electrode **68** relative to the basket electrodes **18**. In the illustrated embodiment (see FIG. **16**), navigation application **A3** interpolates the proximity-indicating outputs to switches "ON" a phantom node PN(**2**, **3**) midway between two electrode nodes N2 and N3, each of which is in a "Close Condition" to the roving electrode **68**. As FIG. **16** also shows, if more two nodes, e.g., N**5**, N**6**, N**9**, and N**10** are ordered to be switched "ON" simultaneously, the navigation application A**3** interpolates by switching "ON" a phantom node PN(**5**, **6**, **9**, **10**) at the geometric center of the three or more electrode nodes N**5**, N**6**, N**9**, N**10**.

c. Spacial sensing (Electrical Field Analysis)

Alternatively (see FIG. **17**), when in the navigation mode, the algorithm of the program **94** embedded with the ASIC **80** can direct the switch manager **90** to generate an electrical field F from either the roving electrode **68** or at least one of the basket electrodes **30** (called the "transmitting electrode"). The electric field F will be characterized, in part, by the physical dimensions and spacing among basket electrodes **18**.

The program **94** also directs the switch manager **90** to condition either the roving electrode **68** or at least one of the basket electrodes **18** to sense electrical potentials in the electric field, which will change based upon the position of the roving electrode **68** relative to basket electrodes **18**. The sensed electrical potentials are communicated by the switch manager **90** to the navigation application A**3**.

The navigation application A**3** includes an embedded navigation algorithm **454**, which analyzes the spatial variations in the electrical potentials sensed within the field, in terms of, e.g., variations in phase, or variations in amplitude, or both, or variations in impedances between the transmitting and sensing electrodes. Knowing these spacial variations in the electrical field, and knowing the physical dimensions and spacing among basket electrodes **18** (which the identification code **100** of the basket **58** provides, or which can otherwise be embedded as empirically derived mathematical coefficients and weighing factors in the navigation algorithm **454**), the navigation algorithm **454** generates a location output **334**. The location output **334** locates the roving electrode **68** within the space defined by the basket **58**, in terms of its position relative to the position of the multiple basket electrodes **18**. The navigation application A**3** updates the display by the GUI **46** of the moving electrode image **324** based upon the location output **334**.

Further details of the use of an electrical field to sense and locate a movable electrode an interior body region can be found in U.S. Pat. No. 5,722,402

d. Spacial Sensing (Wave Form Analysis)

In another alternative embodiment (see FIG. **18**), when in the navigation mode, the algorithm of the program **94** embedded with the ASIC **80** can direct the switch manager **90** to generate an electric wave form output W from either the roving electrode **68** or at least one of the basket electrodes **30**. The shape of the electric wave form output W within the basket **58** will be characterized, in part, by the physical dimensions and spacing among basket electrodes **18**.

The program **94** also directs the switch manager **90** to condition the roving electrode **68** to periodically sense a local electric waveform. The manager **90** communicates the sensed local wave form to the navigation application A**3**. The navigation application A**3** includes a navigation algorithm **454**, which conducts a differential comparison of the waveform output and the sensed local waveform. Knowing the results of the differential waveform comparison, and knowing the physical dimensions and spacing among basket electrodes **18** (which the identification code **100** can provide or which can be otherwise embedded as empirically derived mathematical coefficients and weighing factors in the navigation algorithm **454**), the navigation algorithm **454** generates a location output **336**. The location output **336** expresses the position of the roving electrode **68** relative to the basket electrodes **18**. The navigation application A**3** updates the display the moving electrode image **324** on the GUI **46** based upon the location output **336**.

6. Marking Navigation Data

In a preferred embodiment, the toolbar **296** of the navigation window an INS MARKER control button **390** and a FIND SITE control button **392**. When selected, the control buttons **390** or **392** make it possible to annotate the displayed images **284**L and **284**R.

The INS MARKER control button **390**, when selected, allows the operator to annotate either image **284**L or **284**R by adding an identifier or marker and an associated text comment to selected locations of the image **284**L/R. When selected (see FIG. **19**), the INS MARKER button **390** opens a Markers Control Menu **394**. The Markers Control Menu **394** includes push button controls labeled ADD MARKERS **396**, MOVE MARKERS **398**, DEL MARKERS **400**, and CLOSE **402**.

When the ADD MARKERS button **396** is selected, the application A**3** enables the operator to operate the pointing device **42** to select a spot on either image **284**L or **284**R and, by clicking, drop a shaped bitmap marker **404** (shown in FIG. **19**) on the image. The marker **404** includes an associated number, which the application A**3** assigns in numeric order as markers **404** are created. Once inserted in one image **204**L or R, a corresponding marker **404** is automatically inserted in the other image.

As FIG. **19** shows, when the marker **404** is dropped into position on the image, the application A**3** opens a pop up comments window **406**. The window **406** includes an automatic time stamp **410** and an editable comments field **408**. The operator enters the desired comment into the comment window **406** using the keyboard **40**.

The markers **404** and comment windows **406** can be placed near electrodes nodes on either the foreground or background of the image **284**L/R. The markers **404** and windows **406** mark selected locations that are significant or of interest, such as mapping sites, ablation sites, etc. The physician is thereby better able to remain coordinated and oriented with the displayed image and, therefore, better able to interpret data recovered by the basket **58**.

When the marker control menu **394** is displayed, the application A**3** removes a selected marker **404** and associated comment window **406** when the DEL MARKER button **400** is selected. The MOVE MARKERS button **398**, when selected, allow the operator to drag and then drop a selected marker **404** and associated comment window **406** to a different location on the image **284**L/R.

Selecting the CLOSE button **402** dismisses the marker control menu **394**. The marker(s) **404** and comment window (s) **406** remain on the image **284**L/R. Selecting the SAVE button **314** on the toolbar **296**, as previously described, saves the image **284**L/R together with all current markers **404** and comment windows **406**. Information resident on the entire graphical display, including model image **284**L/R, markers **404**, and associated comment windows **408** are saved as a data file records for storage, retrieval, or manipulation.

Selecting the FIND SITE button **392** opens a dialog box **410** (see FIG. **20**), into which the operator enters an electrode coordinate (A1, B6, etc.). The navigation application A3 draws a flashing circle 412 about the corresponding electrode node on both images 284L/R. The flashing circle 412 remains on the image until another action is taken by the operator.

7. Real Image Navigation Application (A4)

The selection of the REAL IMAGE NAVIGATION push button control 126 runs the real image navigation application A4. The application A4, when executed by the MPU 28, displays a sub-window 416, as shown in FIG. 21, which displays in real-time the image 418 acquired by the imaging device 72.

As can be seen in FIG. 21, the main application control push buttons 120 to 134 still remain in view on the right side of the screen in their original first color, except the selected REAL IMAGE NAVIGATION push button control 126, which changes color when selected.

The application allows the operator to process the image 418 in various ways to achieve different results.

a. Image Comparison

The sub-window 416 of the application A4 displays the image 416 acquired by the fluoroscope or other imaging device 72. This image 416 may be used in association with the virtual image navigation application A3 to help visualize the actual orientation of the basket 58 and roving electrode 68 in the body region.

The sub-window 416 includes a COMPARE control button 420. When selected, the visualize application switches to a new sub-window 422 (see FIG. 22, which displays in a left panel 424 the left panel image 284L of the virtual navigation sub-window 282(generated by the application A3 previously discussed) along with a right panel 426, in which the real-time image 418 is displayed. The orientation control buttons 304(X,Y,Z) and 320 and associated numeric orientation angle fields 306 (X, Y, Z) and 322 present on the virtual image navigation screen 282 are also displayed in the compare window 422. This presentation allows the physician to compare the fluoroscopic or other independent image and manipulate the GUI image 284L to more closely match the view of the real-time image 418. The images 284L and R displayed on the virtual image navigation screen 282 (see FIG. 9) are updates to reflect changes in orientation made using the compare screen 422.

In a preferred embodiment, the applications A3 and A4 permit point-and-drag control by the pointing device 42, to change the shape of the idealized image 284L on either navigation screen 282 or 422, to more closely match the shape of the image 418 as seen in the real-time image panel 426, or using an independent real time imaging system. The shape of the idealized image 284L can be formed by dragging the pointing device 42, for example, to appear in a range of configurations from spherical to a more elongated ellipsoid (when the image 284L depicts a three-dimensional basket 58, as shown in FIG. 22) or to appear in a range of curve radii, when the multiple electrode instrument 12 comprises an elongated, curvilinear structure.

The compare windows 422 includes a SAVE control button 428. When selected, the SAVE button 428 saves the shape characteristic formed by the physician in the compare window 422, along with other image information, as already discussed. Once the idealized image 284L/R are coordinated with the real image 418 through use of the compare window 422, the physician can switch views of the idealized image 284L/R electronically on the navigation screen 282, without further manipulating the real-time imaging device 72.

b. Image Processing

The sub-window 416 of the application A4 (see FIG. 21) also includes specialized file management control buttons, labeled CREATE 430, OPEN 432, SAVE 434, DELETE 436, and EDIT 438.

When the CREATE control button 430 is selected, the application A4 freezes the real-time image 416 (or a prescribed sequence of video images 416) so that it can be grabbed for processing. When the EDIT control button 438 is selected, the operator can mark or annotate the grabbed image or video image sequence with comments, in the same manner permitted by the INS MARKER button 390 of application A3, which has been previously described (see FIG. 19).

When the SAVE control button 434 is selected, the grabbed image or video image sequences, with annotations, can be saved to the hard drive as a data base record file, preferably as part of the patient data base 52, which will be described in greater detail later.

Because real time image files are typically large (e.g. exceeding 50 KB), various compression methods can be used to compress them and thus, save disk space. The compression can be lossy (i.e. when data are retrieved some information may be lost) or lossless (i.e. no data are lost upon retrieval). The compression ratios are higher for lossy compression. For fluoroscopy and ultrasound images, minor data loss is acceptable upon retrieval. In a preferred embodiment, real time video data are stored into patient database 32 using optimal lossy compression. Once saved into the database 32, these images and annotations can be retrieved by selecting the OPEN button 432 for future analyses. The images and annotations, once opened, can be further annotated by selecting the EDIT button 438 (which recalls the MARKERS function), or can be removed from the data base 32 by selecting the DELETE button 436.

c. Image Analysis

The sub-window 416 of the application A4 (see FIG. 21) also includes an ANALYZE IMAGE control button 440. When selected (see FIG. 23), the application A4 executes an embedded graphic analysis function 442. The function 442 electronically process the video input signals 458 to mathematically generate digital three-dimensional basket coordinates 450 and three-dimensional roving electrode coordinates 452. The digital coordinates 450 and 452 are communicated to the navigation processing algorithm 454 of the application A3 to help construct the idealized image 284L/R displayed on the navigation screen 282.

In the illustrated embodiment (see FIG. 23), the basket electrodes 18 and splines and the roving electrode 68 are visualized from two different angles using a biplane fluoroscopy unit 444. The unit 444 includes one fluoro arm 446, which captures a real AP (anterior-posterior) video image, and a second fluoro arm 448, which captures either a real LA090 (left-anterior-oblique) image or a real RA090 (right-anterior-oblique) image of the basket 58. These images are processed through the interface 26 as the video signal inputs 458 to the application A4.

At the same time, the imbedded navigation algorithm 94 in the interface 26 (previously described) receives from the basket electrodes 18 and the roving electrode 68 electrical position-indicating signals. The interface 26 conveys these as electrical signal inputs 456 to the navigation processing algorithm 454 executed by the application A3. As previously described, when the real image analysis function 442 is not enabled, the navigational outputs 334/336 of this algorithm 454 are displayed in graphical form on the image 284L/R.

When enabled by selection of the ANALYZE IMAGE control button 440, the image analysis function 442, the analysis function 442 mathematically computes, based up the video input signals 458, three-dimensional digital basket coordinates **450**. The digital coordinates **450** are inputted to the navigation processing algorithm **454** of the application A3. The application A3 generates a basket image output **466** that takes the real image basket coordinates **450** into account, thereby providing an idealized image **284**L/R that more closely corresponds to the real image **418**.

As FIG. **23** also shows, when enabled, the analysis function **442** also generates, based upon the real image of the roving electrode **68**, three-dimensional roving digital coordinates **452**. The application A3 includes a comparator **464**, which compares the three-dimensional digital roving coordinates **452** to the location output (e.g., **334** or **336**) generated by the navigation algorithm **454**, as previously described (see FIG. **17** or FIG. **18**). The error output of the comparator **464** is communicated to an iterative calibration loop **460**, which adjusts empirically initialized mathematical coefficients and weighing factors assigned to the navigation algorithm **454** to minimize comparison errors. The analysis function **442** thereby provides a self-calibration feature for navigation algorithm **454** of the application A3. The calibrated output **462** is used to construct the display of navigational information on the navigation screen **282**.

8. Test Application (A5)

The selection of the TEST push button control **128** runs the test application A5. The test application A5, when executed by the MPU **28**, displays the test sub-window **468**, as shown in FIG. **24**. As can be seen in FIG. **24**, the main control push buttons **120** to **134** continue to remain in view on the right side of the window **468** in their original first color, except the selected TEST push button control **128**, which changes color when selected.

The test application A5, when executed, conditions the switch manager **90** to apply voltage among the various electrodes **18** and recorder input channels **116** (see FIG. **3**) to verify the ability to operate according to the configuration specified in the Record Configuration window **136** (shown in FIG. **5**). The test application A5 executes a short/open channel test at each input channel pair specified by the operator on the test sub-window **468**. The test application A5 displays the results of the test. The test application A5 also allows the operator to set the local system time.

In the illustrated embodiment (see FIG. **24**), the test sub-window **468** includes a SHORT/OPEN TEST push button control **470**, a lMV TEST push button control **472**, and a **5**MV TEST push button control **474**. The sub-window also includes a RESULTS data fields **476**, **478**, **480** aligned with each test push button control **470**, **472**, and **474**. The sub-window **468** also includes an editable SET TIME data field **482** in HH:MM:SS format.

A START push button control **484** (to start a selected test), a STOP push button control **486** (to stop a selected test), and a CLOSE push button control **488** (to terminal all selected tests and close the test sub-window **468**) are also displayed on the test sub-window **468**.

a. Short/Open Test

In executing a Short/Open Test, the detection of shorted and open electrodes can be performed either "exhaustively" or by specifying particular pairs of inputs and outputs. In the "exhaustive" test, all possible combinations of input and output pins are tested. Although effective in finding all potential malfunctions, such a test takes considerable time. Alternatively, the test can be conducted only between specified pairs of inputs and outputs. Operating speed is considerably increased using such a test protocol.

Upon selection of the SHORT/OPEN TEST button **470** and the START button **484**, the test application A5 configures the switch manager **90** to detect open or shorted electrodes. In the illustrated embodiment, the ASIC **80** includes a constant current source **490** (see FIG. **3**), which can be selectively switched to each of the electrodes **18** and **68** coupled to the interface **26**.

Generally speaking, if the electrode **18**/**68** is outside the patient's body, a voltage condition above a specified high threshold will result when the constant current source is coupled to an open electrode. A detector **492** on the ASIC **80** (see FIG. **3**) senses the occurrence of the high voltage. The detector **492** can also check whether the phase angle is greater than a predetermined limit (e.g., 45°). If prescribed criteria are met, the switch manager **90** returns an Open Electrode signal to the test application A5. The test application generates an Open Electrode message in the associated RESULTS data field **476**. The test application A5 also updates the STATUS field **166** in the recording configuration window **136** (see FIG. **5**) and the STATUS field **226** in the pacing configuration window **208** (see FIG. **7**) indicate an opened electrode condition.

Generally speaking, if the electrode **18**/**68** is inside the patient's body, a low voltage condition below a specified low voltage threshold results when the constant current source **490** is coupled to a shorted electrode. The detector **492** senses the low voltage condition. The detector **492** can also check whether the phase angle meets various criteria. If prescribed criteria are met, the switch manager **90** returns a Shorted Electrode signal to the test application A5. The test application generates a Shorted Electrode message in the associated RESULTS data field **476**. The test application A5 also updates the STATUS field **166** in the recording configuration window **136** (see FIG. **5**) and the STATUS field **226** in the pacing configuration window **208** (see FIG. **7**) indicate a shorted electrode condition.

The absence of an Open Electrode signal and a Shorted Electrode signal is interpreted by the test application A5 as an operational electrode. The test application A5 generates a operational electrode message in the associated RESULTS data field **476**. The absence of information in the STATUS fields **166** and **226** in the recording configuration window **136** and the pacing configuration window **208** likewise indicates an operational electrode condition.

b. High/Low Voltage Tests

Upon selection of the 1 MV TEST button **472** and the START button **484**, the test application A5 configures the switch manager **90** to output a low (1 mV) electrical level for a set period of time to the electrodes. Likewise, upon selection of the **5**MV TEST button **474** and the START button **484**, the test application A5 configures the switch manager **90** to output a high (5 mV) electrical level for a set period of time to the electrodes.

To accommodate these test procedures, the ASIC **80** includes a high voltage source **494** and a low voltage source **496** (see FIG. **3**), which are coupled to the outputs when so commanded by the test application A5. The voltages thus applied are sensed at the associated electrodes. The absence of the sensed voltages, or the sensing of different voltage values, indicates a faulty condition in the hardware interface **26**. The test application A5 generates a an appropriate message in the associated RESULTS data fields **478** or **480**.

9. Print Application (A6)

The selection of the PRINT push button control **130** runs the print application A6. The print application A6, when executed by the MPU **28**, displays the pint sub-window **498**, as shown in FIG. **25**. The main control push buttons **120** to **134** continue to remain in view on the right side of the print window **498** in their original first color, except the selected PRINT push button control **130**, which changes color when selected.

The print window **498** provides an array of push button controls, which permits the operator to select, by keyboard entry or pointing device **42**, one or more screen displays to be printed on the printer. For example, the illustrated embodiment offers the buttons labeled for the following print selections: Record Configuration information **500**, Record Sequence information **502**, Pace Configuration information **504**, Pace Sequence information **506**, the Left Navigational Image **508**, the Right Navigational Image **510**; the Real Image Freeze **512**; all or selected data base items of the Patient Data Base **514**(as will be described later).

When the PRINT control button **522** is selected, the print application A6 compiles and formats the selected information for output to the printer **34**. The print application A6 also appends pre-designated patient information from the data base to the printout.

After a printing operation has begun, the print application A6 displays status information in a PRINT STATUS field **524**. A CANCEL PRINT button control **526** allows the operator to cancel the current printing operation. The CLOSE control button **528** dismisses the print window **498** and returns control to the application being executed at the time the PRINT button **130** was selected.

10. Service Application (A7)

The selection of the SERVICE push button control **132** runs the service application A7. The service application A7, when executed by the MPU **28**, displays the service sub-window **516**, as shown in FIG. **26**. The main control push buttons **120** to **134** remain in view on the right side of the window **516** in their original first color, except the selected SERVICE push button control **132**, which changes color when selected.

The service window **516** displays a dialog box **518**, which contains input fields for the operator to enter a SERVICE IDENTIFICATION **520** and a PASSWORD **530**. When the OKAY button **532** is selected, the service application A7 accepts the inputs in the fields **520** and **530** and compares them to known identification and password codes embedded in the application A7. When the inputs match the known codes, the service application A7 terminates the GUI **46** and returns control of the MPU **28** to the underlying operating system **44**. The service application A7 provides access to the underlying operating system **44** and associated host computer functions only to authorized service personnel.

Selection of the CANCEL button **534** dismisses the service window **516** and returns control to the application being executed at the time the SERVICE button **132** was selected.

11. The Event Log Function (F1)

The operating system includes an Event Log Function F1 (see FIG. **1**), which retains in system memory a record of specified critical events as they occur during the course of a given procedure. For example, in the illustrated embodiment, critical events can include: the selection of the APPLY control button **160** in the Recording Configuration window **136** (FIG. **5**); the selection of the APPLY control button **240** in the Pacing Configuration window **208** (FIG. **7**); changes in the configuration of the pacing electrodes shown in the configuration control window **208** (FIG. **7**); the times at which the switch manager **90** applies a configured record sequence or a configured pace configuration; and the selection of the DISCONNECT STIMULATOR button control **242**.

In the illustrated embodiment, the Event Log Function F1 records the specified events by time (read from the operating system **44**) in the event log **50** (see FIG. **1**). The event log data base **50** indexes the recorded events according to patient information, the coordinates of the roving instrument, the recording configuration name, the pacing electrodes, and comments (which identify the nature of the event).

The selection of the EVENT LOG control button **134** toggles display of the contents of event log for the current session on and off. When the control button is selected on, a pop-up window **536** is displayed on the navigation screen **282** (see FIG. **27**). The pop-up window **282** has data field entries, provided from the event log data base **50**, which are arranged under headers for Time **538**, Roving Instrument Coordinates **540**, Recording Configuration Name **542**, Pacing Electrodes **544**, and Comments **546**. When active, the operator can input additional information in the Comment field **546**. When the control button **134** is selected off, the pop-up window is not displayed, although the Event Log Function F1 still continues to record events in the event log data file **50**.

12. Patient Data Base Function (F2)

In the illustrated embodiment (see FIG. **1**), the operating system **44** includes a Patient Data Base function F2. The function F2 makes it possible, during the course of a given procedure, to store, retrieve, and manipulate patient-specific and related procedure-specific information in a patient data base **52** resident on the hard drive **32**. The Patient Data Base function F2 creates data base items incorporating patient-specific and related procedure specific information, comprising, e.g., patient name and other identifying information, together with navigation images **284**L/R generated by the navigation application A3; the threshold sensitivity set using the sensitivity Adjustment window **330** in the navigation application A3 (see FIG. **15**); catheter configuration and recording configuration and sequences generated by the recording protocols application A1; pacing configuration and sequences generated by the pacing protocols application A2; physician's comments and annotations inserted by use of the Markers Control Menu **394** in the navigation application A3 (see FIG. **19**); anatomic features positions inserted using the Features button **372** in the navigation application A3 (see FIGS. **9** and **13**); mapping information generated through use of the binary map selection menu **368** by the navigation application A3 (see FIGS. **11** and **12**); contents of the Event Log **50**; and fluoroscopy, ultrasound, or other medical images generated by the real image application A4 (see FIG. **21**).

The Patient Data Base function F2 compiles patient-specific and procedure-specific information as disk files saved to the hard disk **32**. The disk files in the data base **52** are organized in study subdirectories based upon the patient's name. The data base items can also be manipulated by the operator, e.g., selected data base files can be accessed or opened upon command for editing, deletion, searching, listing, sorting, compiling, and printing.

a. Establishing Patient Data Base Information

The Patient Data Base function F2 can be implemented in various ways. In the illustrated embodiment, the Patient Data Base function F2 opens a Patient Data Window **548** (see FIG. **28**) at the time that the Toolbar **296** (previously described) is first generated by the navigation application A3 in the course of a given procedure, as this event occurs at the beginning of a given study.

The Patient Data Window **548**, when opened, requires the physician to enter data about the particular patient and procedure, to thereby establish a new patient/study subdirectory in the data base **52**, before the new study is allowed to proceed. Selecting the Cancel button **616** dismisses the Data Window **548** without establishing a new patient/study subdirectory, returning the operator to the navigation window **282** for the current study.

To create a new patient/study subdirectory in the data base **52**, and thereby enable the new study to proceed, the physician enters the name of the patient and a numeric three digit sequence number in a Patient field **550** of the Data Window **548**. The Patient field **550** includes a drop down menu control **572**, listing existing patient names from which the operator can select. Once the name is entered, the function F2 detects existing subdirectories for the same name and creates an addition study subdirectory, or otherwise a new patient directory is established and the new study subdirectory created. The function F2 assigns a name to the new study in a Study Name field **554**, with an associated time marker **556**. The patient three digit numeric sequence serves as a study name extension.

The physician can enter in the Text field **558** of the Data Window **548** additional information or comments regarding the patient, such as the patient's ID number, age, etc., which the physician wants to save as part of the patient/study record. The physician can also enter diagnostic information, e.g., heart tissue pacing data; or therapeutic information, e.g., heart tissue ablation data; or identify the attending physician or staff personnel. The Data Window **548** includes an Open Button **562**, which recalls the most recent study record for the patient, and inserts information in the Text field **558** of the existing record into the Text field **558** of the new study record.

The physician clicks the New Study button **552** of the Data Window **548**. The function F2 automatically saves the patient/study information to the newly created subdirectory.

When the New Study button **552** is selected, the function F2 opens an image selection dialog box **564** (see FIG. **29**). The dialog box **564** prompts the physician to set the idealized image viewing angles. Selecting the Reset button **568** starts the new study with default idealized image views in the left and right panels **286** and **288**(which is the same function as the Reset View button **312** on the Toolbar **296**, as shown in FIG. **9**). Once the new study is underway, the physician can proceed to customize the default left and right panel images **284**L/R, as previously described.

Alternatively, selecting the Existing View button **570** in the image selection box **564** starts the new study with the same markers, binary maps, features, comments, sensitivity threshold, and views active in the immediately preceding study. This option allows the physician to quickly switch among different diagnostic or therapeutic protocols (each constituting a "study") on the same patient using the same structure **58** in the same heart chamber.

Once the view is selected, the dialog box **564** and Data Window **548** are dismissed, and control returns to the navigation window **282** (FIG. **9**). The new study commences, with the selected image views displayed in the navigation window **282**.

During the new study, the physician can call upon all the features of the applications **A1** to **A7** and function **F1** as already described. For example, the physician can set up binary maps, in the manner previously described (see FIG. **11** and **12**), or mark anatomic features (see FIG. **13**). The physician can set up markers **404** and comment windows **406** in association with the selected image views, as FIG. **19** shows. In the comment windows **406**, the physician can include further information identifying the procedure, diagnostic information, therapeutic information, or otherwise annotate the image **284**L/R. By clicking the SAVE button **314** on the Toolbar **296** at desired times, the entire graphical display, including the idealized image **284**L/R, markers **406**, and associated comment windows **406** are saved as a data file in the patient/study subdirectory, uniquely associated with the particular study and particular patient for storage, retrieval, or manipulation.

b. Manipulating Patient Data Base Information

In the illustrated embodiment, selection of the Patient Data Base button **514** in the print window **498** (FIG. **25**) opens a patient record dialog box **574** (see FIG. **30**). The dialog box **574** includes a Patient Name field **576** and a Study field **578**, in which the operator can specify a particular subdirectory. The fields **576** and **578** each include a menu control button **580**, which, when selected, opens a drop down menu listing patient names and studies residing in the data base **32**.

Selection of the Open button **582** opens a directory box **584** (see FIG. **31**), which list the files **618** contained in the specified subdirectory. The highlighted file can be opened for viewing (by selecting the View button **586**); or printed (by selecting the Print button **588**); or saved (by selecting the Save button **606**).

Alternatively, selecting the Find button **590** in the window **576** (see FIG. **30**) opens a Find/Sort box **592** (see FIG. **32**). The Find/Sort box **592** provides access to special functions that compile, search, manipulated, or filter the records in the patient data base **52** in conventional ways, e.g., by use of a SEARCH DATA BASE control button **594** (which allows key-word or file searching), a LIST DATA BASE control button **596** (which lists data base files in established directory and subdirectory order), and a SORT DATA BASE **598** control button (which allows files be arranged, e.g., chronologically, by file type, etc.). The results of the requested function are displayed for viewing in a Results field **599** which can be opened for viewing (by selecting the View button **604**); or printed (by selecting the Print button **600**); or saved (by selecting the Save button **602**). Selecting the Close button **620** dismisses the Find/Sort box **592** and returns control to the Patient Records window **574** (see FIG. **30**). Selecting the close button **622** in the Patient Records Window **574** dismisses the window **574** and return control to the print selection window **498** (as shown in FIG. **25**).

As FIG. **1** shows, a communications link **610** allows patient record information to be transmitted from the hard drive **32** to a central data storage station **612**. A network **614** of local or remote systems **10**, **10**(A), **10**(B), and **10**(C), each having all or some of the features described for system **10**, can be linked to the central data storage station **612**, by an Internet-type network, or by an intranet-type network. The network **614**, all linked to the central data storage station **612**, allows patient-specific data base records for many patients at one or more treatment facilities to be maintained at a single location for storage, retrieval, or manipulation. In the illustrated embodiment (see FIG. **30**), the patient record dialog box also includes an IMPORT control button **608**. When selected, the button **608** allows patient/study data base files residing on the station **612** to be up loaded into the patient data base **32** resident on the system **10**. Conversely, the various save functions in the directory box **584** (see FIG. **31**) or the Find/Sort box **592** (see FIG. **32**) can specify down loading patient/study data base files from the MPU **28** to the central data storage station **612**.

Various features of the invention are set forth in the following claims.

What is claimed is:

1. A method for deploying a structure in an interior body region of a patient, the structure including an operative element coupled to a controller, which establishes an operating condition for the operative element to perform a diagnostic or therapeutic procedure in the interior body region, the method comprising:

generating a first display comprising an image of the structure at least partially while the operative element performs the procedure,

generating a second display comprising one or more data fields reflecting the operating condition of the controller, and

deploying the structure in the interior body region while selecting the first display or the second display for viewing on a display screen.

2. A system comprising:

an electrode structure which, in use, is deployed in contact with heart tissue;

a controller coupled to the electrode structure operating to establish an operating condition to perform a diagnostic or therapeutic procedure, and

an interface comprising

a display screen, and

an interface manager coupled to controller and the display screen, wherein the interface manager performs a first function to generate a first display comprising an image of the electrode structure at least partially while performing the procedure, a second function to generate a second display comprising one or more data fields reflecting the operating condition of the controller, and a third function to enable selection of the first display or the second display for viewing on the display screen.

3. The system of claim **2**,

wherein the controller generates commands to establish the operating condition at least partly in response to operator input, and

wherein the interface manager includes an input to receive operator input and to transmit operator input to the controller.

4. The system of claim **3**,

wherein the second function generates a data field for operator input.

5. The system of claim **2**,

wherein the second function includes generating data fields defining a pacing configuration for the electrode structure to conduct pacing pulses from a stimulator coupled to a controller.

6. The system of claim **5**,

wherein the interface manager further performs a file manager function to off-load or up-load data files defining the pacing configuration.

7. The system of claim **2** or **6**,

wherein the second function includes generating data fields defining a sequence of pacing pulses to be applied to the electrode structure from a stimulator coupled to the controller.

8. The system of claim **7**,

wherein the interface manager includes a file manager function to off-load or up-load data files defining the sequence.

9. The system of claim **2**,

wherein the second function includes generating data fields defining a recording configuration of the electrode structure to conduct electrical signal data to a recorder coupled to the controller.

10. The system of claim **7**,

wherein the interface manager further performs a file manager function to off-load or up-load data files defining the recording configuration.

11. The system of claim **2** or **9**,

wherein the second function includes generating data files defining a sequence of conveying electrical signal data from the electrode structure to a recorder coupled to the controller.

12. The system of claim **11**,

wherein the interface manager further performs a file manager function to off-load or up-load data files defining the sequence.

13. The system of claim **2**,

wherein the interface manager further performs a fourth function to generate a third display comprising one or more data base fields reflecting a test condition for the controller or the electrode structure, and

wherein the third function includes enabling selection of the first display or second display or third display for viewing on the display screen.

14. The system of claim **2**,

wherein the interface manager further performs a service function to generate a service display comprising one or more data base fields reflecting a service condition, and

wherein the third function includes enabling selection of the first display or second display or service display for viewing on the display screen.

15. The system of claim **2**,

wherein the first display comprises a real image of the electrode structure acquired by an imaging device.

16. The system of claim **2**,

wherein the first display comprises an idealized graphical image of the electrode structure.

17. The system of claim **2**,

wherein the interface manager, when performing the first function, may alter appearance of the image in response to operator input.

18. The system of claim **17**,

wherein the interface manager, when performing the first function, may alter the orientation of the image.

19. The system of claim **17**,

wherein the interface manager, when performing the first function, may alter the shape of the image.

20. The system of claim **17**,

wherein the interface manager, when performing the first function, may alter view aspects of the image.

21. The system of claim **2**,

wherein the interface manager is configured to insert annotations in the first display in response to operator input.

22. The system of claim **2**,

wherein the interface manager is configured to mark one or more regions of the first display in response to operator input.

23. The system of claim **2**,

wherein the first function includes generating in the first display an output showing location of a roving element, deployed in the patient, relative to the electrode structure.

24. The system of claim **2**,

wherein the first function includes generating in the first display a proximityindicating output showing the proximity of a roving element, deployed in the patient, to the electrode structure.

25. The system of claim **2**,

wherein the controller acquires output from the electrode structure, and wherein the first function includes generating markers on the image in response to the output acquired by the controller.

26. The system of claim **2**,

wherein the interface manager is configured to generate a graphical user interface that includes the first and second displays.

27. The system of claim **2**,

wherein the third function includes generating an icon on the display screen which, when activated, selects the first display or the second display for viewing on display screen.

28. The system of claim **27**,

wherein the display screen includes a first display region and a second display region, and

wherein the third function includes displaying the icon in the first display region and the first display or the second display in the second display region.

29. The system of claim **27**,

wherein, in response to activation of the icon, the third function includes opening a selected one of the first display and second displays for viewing in the second display region while closing the other one of the first or second displays to viewing.

30. The system of claim **2**,

wherein the interface manager includes an output to off-load data relating to at least one of the first and second displays.

31. The system of claim **2**,

wherein the interface manager includes an input to up-load data relating to at least one of the first and second displays.

32. The system of claim **2**,

wherein the interface manager includes an output to process data relating to at least one of the first and second displays as a data base record for storage, retrieval, or manipulation.

33. The system of claim **32**,

wherein the output includes a storage medium.

34. The system of claim **2**,

wherein the interface manager includes an input to receive patient data identifying the patient and an output to process patent data as a data base record for storage, retrieval, or manipulation.

35. The system of claim **34**,

wherein the output processes data relating to at least one of the first and second displays in association with the patient data.

36. A method for examining myocardial tissue comprising the steps of

deploying an electrode structure in contact with myocardial tissue,

generating a first display comprising an image of the electrode structure,

generating a second display comprising one or more data fields reflecting an operating condition of the electrode structure, and

causing the electrode structure to either pace myocardial tissue, or record electric events in myocardial tissue, or both, while selecting the first display or the second display for viewing on a display screen.

37. The method of claim **36**,

and further including the step of ablating myocardial tissue.

38. The method of claim **37**,

wherein the step of generating the first display includes generating an idealized graphical image of the electrode structure.

39. The method of claim **37**,

and further including the step of altering appearance of the image in the first display in response to operator input.

40. The method of claim **37**,

and further including the step of altering the operating condition of the electrode structure in response to operator input.

41. The method of claim **37**,

and further including the step of communicating operator input through the first display or the second display to alter the operating condition of the electrode structure.

42. The method of claim **36**,

wherein the step of generating the first display includes generating a real image of the electrode structure acquired by an imaging device.

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